ICS Chartr 200

ICS Chartr EP 200

Installation and Startup Guide

Part No. 7-50-05700

otometrics
MADSEN · AURICAL · ICS

ICS Chartr 200

ICS Chartr EP 200

Installation and Startup Guide

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0459

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Technical support

Please contact your supplier.

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1 Introduction

The *ICS Chartr EP 200 Installation and Startup Guide* is intended for users of the system. It begins with step-by-step instructions for setting up records, preparing the patient, collecting data using the GN Otometrics-supplied default settings, reviewing data, and preparing reports. The Installation Reference section provides information on setting up the hardware followed by instructions for performing the installation calibration requirements. The Guide is organized as follows:

- Prepare System for Data Collection
- Prepare Patient for Testing
- Collect Patient Data
- Review Collected Data
- Print Patient Report
- Maintenance and Troubleshooting
- Safety
- Technical Specifications
- Installation Reference
- Diagnostic Calibrations

Once you are comfortable with the basics, take the time to explore the extensive capabilities of the ICS Chartr EP 200 system.

1.1 Device Description

TheICS Chartr EP 200 system with VEMP Monitor incorporates hardware enabling the capabilities of the two predecessor devices to be offered as a single device.

The ICS Chartr EP 200 system can be configured for a wide variety of electrophysiological tests, and it can be programmed for single protocol or linked protocol operation. The user can select or change the default parameters for a particular test. The VEMP monitor is used to provide biofeedback by monitoring the state of a muscle during Vestibular Evoked Myogenic Potential testing using surface electromyography.

1.2 Intended Use

The ICS Chartr EP 200 system is indicated for auditory or vestibular evoked potential testing as an aid in detecting hearing loss, hearing and vestibular related functions, and lesions in the auditory pathway.

The ICS Chartr EP 200 VEMP Monitor is a biofeedback device capable of monitoring a muscle at rest or in function by means of surface electromyography.

1.3 Intended User

This manual describes the use of the device in combination with the software. Readers are assumed to have prior knowledge of the medical and scientific facts underlying the procedure. For this reason, the examination methods are mentioned only to the degree that is necessary for a correct, safe application of the ICS Chartr EP 200 system.

1.4 Caution

Federal Law restricts this device to sale by or on the order of a licensed physician.

1.5 Other Resources

This Installation and Startup Guide is an introduction to ICS Chartr EP 200. For more information, please refer to the following.

1.5.1 ICS Chartr EP User Manual

The *ICS Chartr EP User Manual* provides information on all aspects of the ICS Chartr EP 200 system including:

- Functional description of each window and dialog box
- Advanced Procedures
- Data Collection and Analysis
- Archiving Options
- Customizing Reports
- Troubleshooting

Note · *The User Manual can be accessed through Help in the software.*

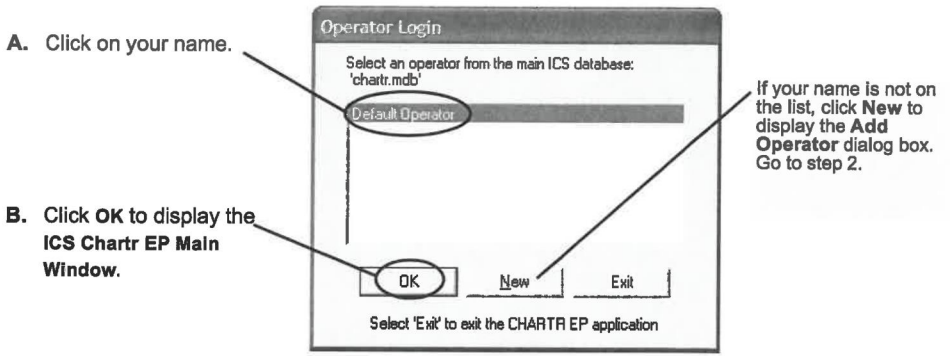
1.5.2 GN Otometrics Customer Support

Otometrics Customer Support is available at www.otometrics.com or contact your local distributor.

2 Prepare System for Data Collection

2.1 Step 1 System Startup and Operator Login

1. Press the Power button on the EP PC and wait for the Windows® Desktop to display.
2. Double-click (ICS Chartr EP icon) to display the **Operator Login** dialog box.
   Alternate: Click **Start** on the Taskbar and select **Programs > GN Otometrics > ICS Chartr EP**.
3. Select an operator from the list.


A. Click on your name.
B. Click **OK** to display the **ICS Chartr EP Main Window.**
Operator Login
Select an operator from the main ICS database: 'chartr.mdb'
Default Operator
OK
New
Exit
Select 'Exit' to exit the CHARTR EP application
If your name is not on the list, click **New** to display the **Add Operator** dialog box. Go to step 2.

Operator Login Dialog Box

4. Go to 2.3 Step 3 Study Main Window ▶ 14

2.2 Step 2 Add an Operator

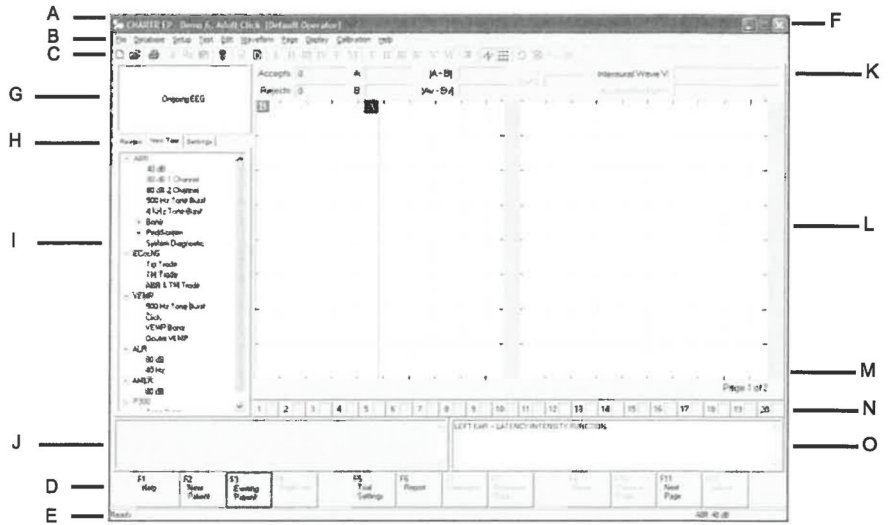
1. Type the requested information.

Add Operator Dialog Box

2. Click **OK** to add your name to the operator list and display the **ICS Chartr EP Main Window**.
3. Go to 2.3 Step 3 Study Main Window ▶ 14.

2.3 Step 3 Study Main Window

1. Review each area of the ICS Chartr EP Main Window and its function.



ICS Chartr EP Main Window

	Areas displayed with or without patient selected	Function/Purpose
A	Title bar	View patient and operator names

	Areas displayed with or without patient selected	Function/Purpose
B	Menu bar	Select program options
C	Toolbar	Quick access and labeling waveforms
D	Function/Operation keys	Select program options
E	Status bar	View program information
F	Maximize/Minimize Close buttons	Toggle between testing and review modes

	Additional areas displayed with patient selected	Function/Purpose
G	Ongoing EEG box	Display EEG waveforms during data collection
H	Tabs - Review, New Test, and Settings	Select a tab to review data, select a protocol, or change protocol settings
I	Test Lists - New or Review	Depending on tab selected, displays test procedures available (New Test tab) or performed (Review tab).
J	Calculation box	View waveform calculations

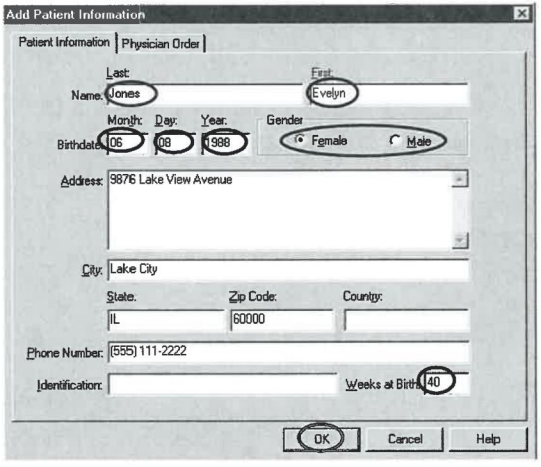
	Additional areas displayed with patient selected	Function/Purpose
K	Waveform data	Displays the number of accepted sweeps and the number of rejected sweeps during collection. Displays Cursor A location (ms), Cursor B location (ms), the difference between Cursor A and B latency (A – B), the difference between Cursor A and B amplitude (Av – Bv), the EMG value (VEMP only), the Interaural Wave V (IT5), and the Asymmetry Ratio (VEMP only). **Note** · *VEMP monitoring is available only if the VEMP monitor application has been included.*
L	Waveform work area	View collected waveforms
M	X-axis labels (area indicated by gray rectangle)	When waveforms with the same sweep time and delay are displayed, the X-axis divisions are labeled in ms
N	Waveform bank numbers	Select waveform by number
O	Waveform page comments box	Type comments to be saved with waveforms

2. Click F1 Help for additional information.
3. Go to 2.4 Step 4 Set up Patient Record ▶ 16.

2.4 Step 4 Set up Patient Record

1. Click **F2 New Patient** on the Main Window to display the **Add Patient Information** dialog box.

2. Type/select the requested patient information.



Add Patient Information Dialog Box

A. Type this information:
- Name (last, first) [required]
- Birthdate [required]
- Address, City, State, Zip Code
- Telephone Number
- Identification (i.e., medical record number)
- Weeks at Birth [required]

B. Select the Gender [required].

3. Click **OK** to create a patient record.
4. Go to 2.5 Step 5 Select Referring Physician and Facility ▶ 17.

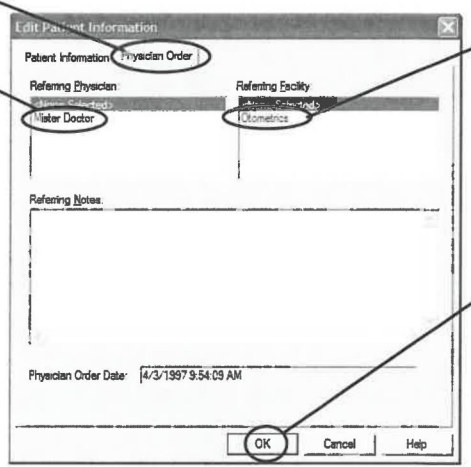
2.5 Step 5 Select Referring Physician and Facility

1. Click the **Physician Order** tab.

2. Select the **Referring Physician** and **Referring Facility.**

A. Click the Physician Order tab.

B. Click on the Referring Physician's name.



C. Click on the Referring Facility's name.

D. Click **OK.**

If the Referring Physician is not on the list, go to 6.5 Step 28 Set up Referring Physician Records ▶ 86.

If the Referring Facility is not on the list, click **None Selected** or go to .6.6 Step 29 Set up New Referring Facility ▶ 88

Add Patient Information Dialog Box

3. Click OK to save the information on both tabs.
4. Go to 2.3 Step 3 Study Main Window ▶ 14.

3 Prepare Patient for Testing

3.1 Step 6 Patient Preparation

Before preparing the patient, turn on the Chartr EP 200 unit and launch the Chartr EP software.

EP tests are best performed on a patient who is quiet, comfortable, and cooperative. If the patient is active, the test time may be longer and the test results may be compromised by a high level of noise (acoustic or myogenic) during the recording.

3.1.1 Supplies Required

The following supplies should be available in the test area:

- NuPrep™ electrode prep, or other skin prep materials.
- Gauze pads or cotton swabs for application of skin prep.
- Electrodes (non-disposable or disposable)
  - Braid or tape electrodes together to reduce noise and for better performance.
  - Use non-disposable electrodes of the same metal type (i.e., silver, gold, etc.).
  - Non-disposable electrodes do not last forever. Replace the electrodes if noisy recording persists or impedances are high.

- Clean and rid non-disposable electrodes of old paste.
- Check the expiration date if disposable electrodes do not adhere.
- Electrode jumper.
- Conductive paste for non-disposable electrodes.
- Cotton balls and/or tape for adhering the electrodes in place.
- Disposable insert earphone eartips for adults and pediatrics.

3.1.2 Test Room Setup

In order to obtain clean, accurate results, the patient should be comfortable. The patient should preferably be lying supine or reclined in a comfortable chair with head and leg support.

Try out the chair or table and lie there for awhile. Are you comfortable? Pillows and blankets should be available to ensure patient comfort.

Instruct the patient to keep his/her eyes closed and relax. Let the patient know that sleeping is the optimal state.

Turn off the lights to encourage relaxation. If the room has fluorescent lights, it is best if these are off as they emit noise. If the lights are on a dimmer switch, make sure the switch is not in a mid position as this can cause noise.

Position the patient away from any devices or sources that cause electrical artifact (i.e., computer monitors). Make sure all cell phones and pagers are off (not just silenced) during data collection.

3.1.3 Skin Preparation

Prepare the skin at the electrode site in order to obtain clean, accurate recordings. To prepare each site, use electrode prep on a cotton swab or gauze and scrub the area where the electrode will be placed. Remember the electrode is not that large, so it is more efficient to accurately scrub the small area where the electrode will be placed than to scrub haphazardly on a large surface area.

- If using non-disposable electrodes, fill the cup of the electrode with a pea-sized amount of conductive paste. Place the electrode on the prepared site and then secure it with a little cotton or tape. When using a Cz placement, it is best to use non-disposable electrodes. If the patient has a lot of hair product, place an alcohol pad at the electrode site for a minute to dissolve the hair product.
- If using disposable electrodes, it is best to use a dry prep. The use of alcohol can dry out the skin too much and cause the electrode not to adhere. If using a wet prep, wipe the skin clean of excess moisture before placing the disposable electrode.

Go to 3.2 Step 7 Apply Electrodes ▶ 23 for information on electrode montages.

3.1.4 Cleaning Non-Disposable Electrodes

Use clean electrodes. Electrodes that are not properly cared for will result in noisy, inaccurate data, and high impedances, and can also cause trending in the waveform (the rising or falling of the waveform away from the baseline).

- To clean paste off of the electrodes, use a soft toothbrush (i.e., infant toothbrush) and some warm water. Do not leave electrodes soaking in water for hours. Handle the electrode wires with care as not to break them.
- If using silver chloride, verify that the chloride has not chipped off. To re-chloride the electrodes, place only the cup of the electrode into a small amount of chlorine bleach. Soak electrodes for only 20 minutes. Do not let the wires touch the chlorine bleach.

3.1.5 Listening Check

Perform listening checks routinely to ensure that the equipment is functioning properly.

- Using a person who has auditory thresholds below 10 dB, make sure they can hear a very faint sound for each stimulus type, and transducer at 0 to 5 dB.
- If the person cannot hear the stimuli, contact the manufacturer or your local representative to troubleshoot your unit.
- See 10.5 Establish Normal Hearing Level Thresholds ▶ 125.

3.1.6 Position Chartr EP (USB) Preamp on the Patient

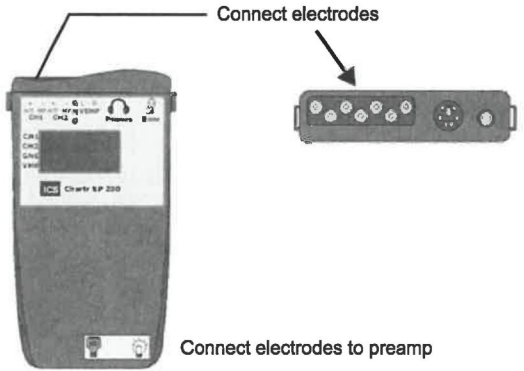
The ICS Chartr EP 200 system is supplied with a lanyard and a shoulder harness. The lanyard is used to hang the preamp around the patient's neck and rest on the patient's chest. However, if the patient has an implantable device (e.g., pacemaker), this is not the best option as the pacemaker may add noise into the EP tracings. The shoulder harness is used to drape the preamp over the patient's shoulder or over the back of the patient's chair/recliner.

3.2 Step 7 Apply Electrodes

Apply the electrodes to the patient. Use an appropriate electrode/transducer combination for the data being collected and the patient's status. The system applies labels to collected waveforms based on the stimulated ear.

3.2.1 Electrode Montages

Below are proper connection of electrode wires into the Chartr EP (USB) preamplifier for 1 and 2 channel recordings for ABR, ECochG, and VEMP. These electrode montages are commonly used for data collection. These are not exclusive and other montages may be appropriate for data collection.

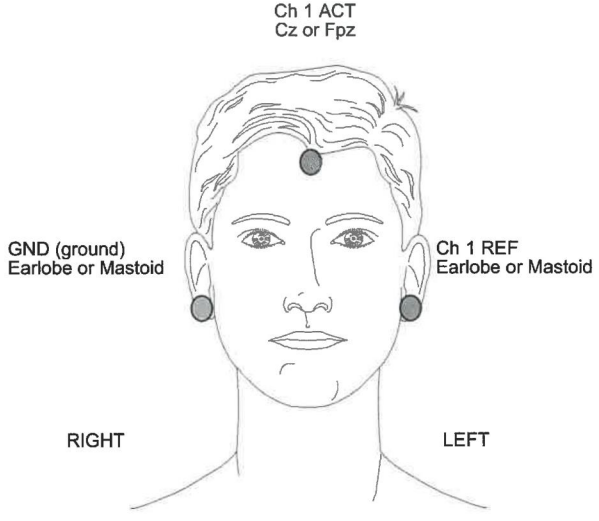


3.2.2 1-Channel Recordings

Please note that 1-Channel recordings should only have 3 electrodes connected to the patient preamplifier (Ch 1 ACT, Ch 1 REF, and GND - ground). Channel 2 electrode jacks are not used. Jumpers should not be connected. Leaving a jumper or electrode lead connected can result in inaccurate data and may introduce noise into the recording.

AUDITORY BRAINSTEM RESPONSE MONTAGES

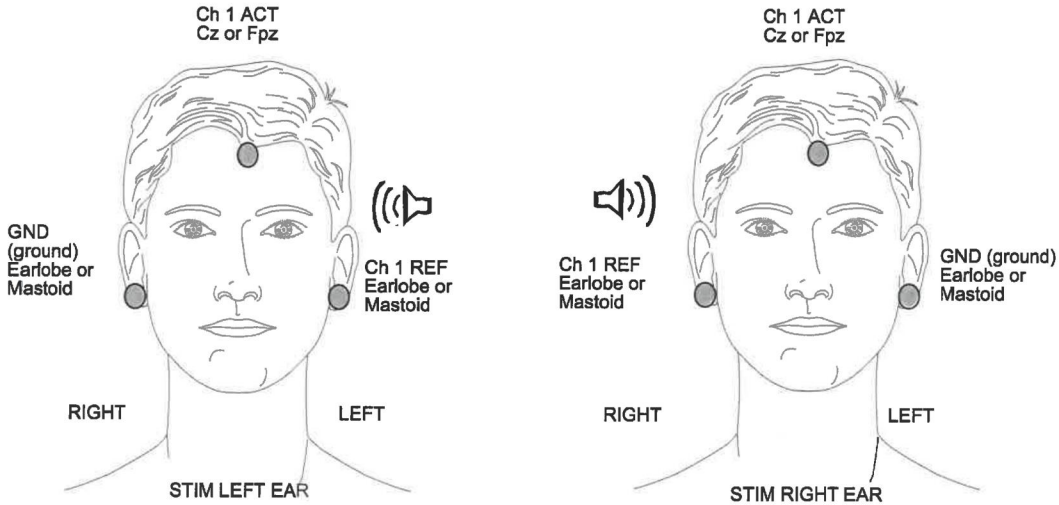
1-Channel ABR
ELECTRODE SWITCHING ON



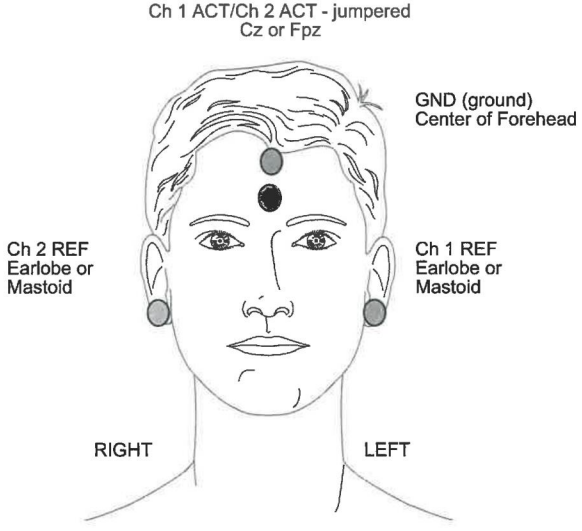
When performing bone conduction ABR, always place the refrence electrode and the ground on the front of the earlobe.

Caution · *If an alternate montage is used with Electrode Switching ON, the data collected will be inaccurate.*

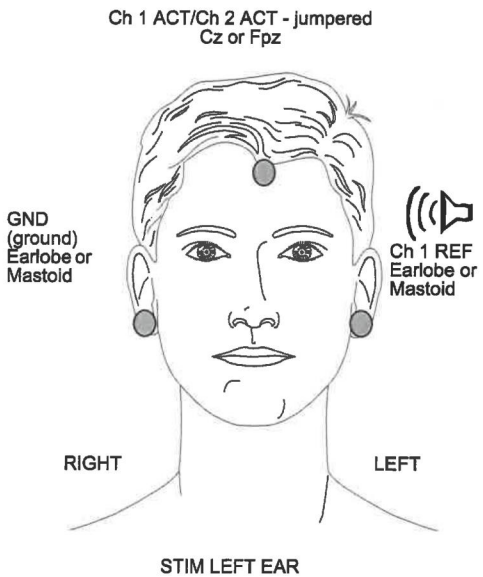
1-Channel ABR
ELECTRODE SWITCHING OFF
Manually Switching Electrodes is Required

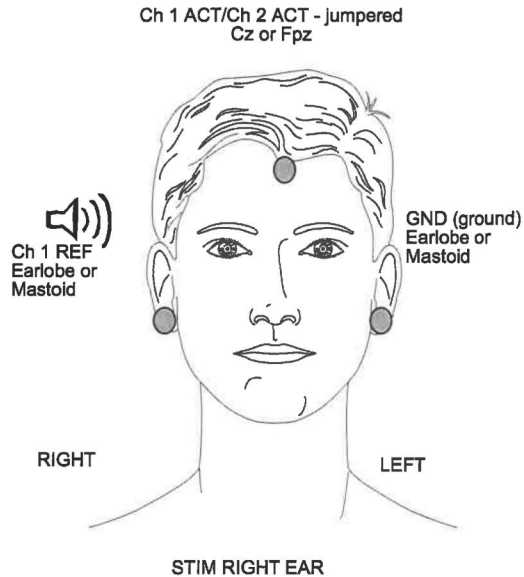


2-Channel ABR

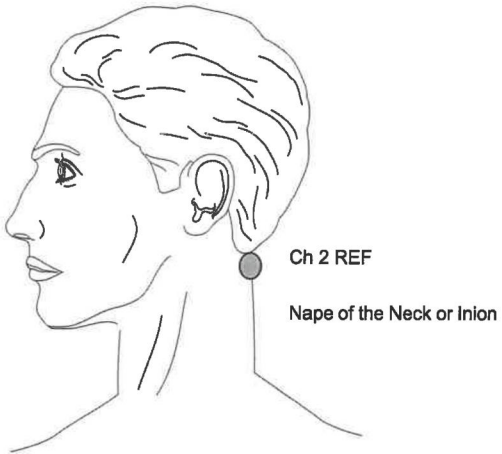


2-Channel ABR
Wave V Enhanced for Infants
Channel 1 - IPSI Recording
Channel 2 - NAPE Recording





2-Channel ABR
Wave V Enhanced for Infants
Channel 1 - IPSI Recording
Channel 2 - NAPE Recording



3.2.3 Tips for TM (tympanic membrane) ECochGtrode

Always perform an otoscopic inspection before placing the TM electrode. Make sure that the ear canal is clear of cerumen. Do NOT place the TM electrode if the patient has a tympanic membrane perforation. To assist in reducing impedance, place 2cc of saline into the ear canal and then drain the ear. Do NOT place saline in the ear if planning to perform VNG/ENG calorics on the same day.

Instruct the patient that a small flexible tube will be inserted into the ear. The patient may feel a little pressure and may hear a "thud" when the end of the electrode touches the tympanic membrane.

Place a very small amount of conductive gel over the hydrogel end of the TM ECochGtrode making it slick and less sticky. Too much conductive gel can plug the insert or make removal difficult.

The ear canal should be in direct light when placing the electrode. Using a microscope or headlamp is appropriate.

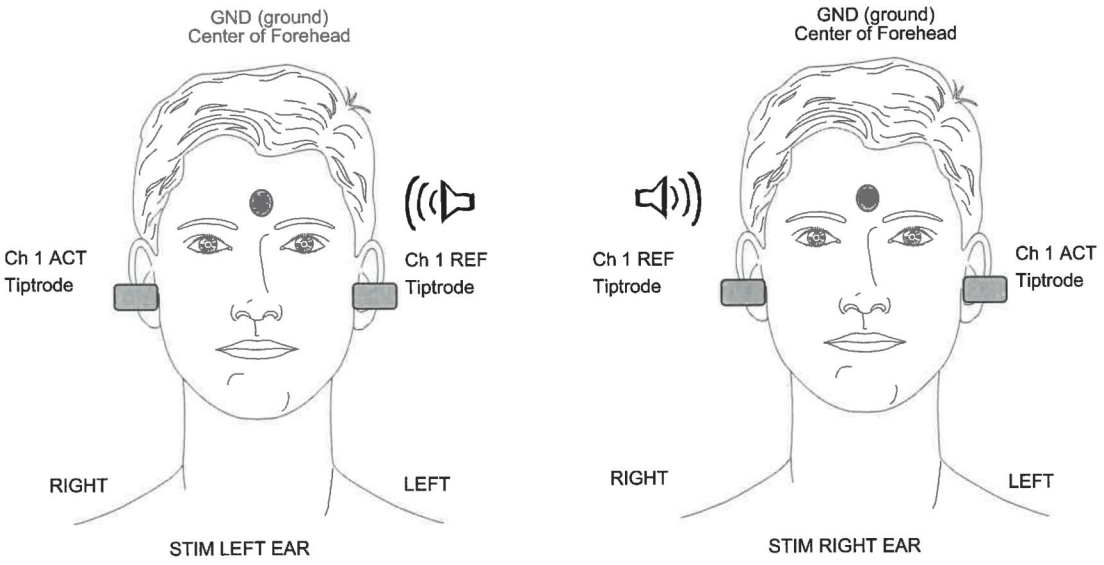
After the TM ECochGtrode is in place, secure the cable to the patient so that the weight of the cable does not pull the electrode out of the ear.

Insert the foam eartip into the ear and on top of the TM ECochGtrode tubing. Hold the tubing of the TM ECochGtrode when inserting the foam eartip so that the electrode is not pushed against the patient's tympanic membrane.

Electrode impedance will be very high for the TM ECochGtrode (>20 K Ohms) and will result in a large inter-electrode impedance difference. Because the TM ECochGtrode is closer to the neural generation source, the inter-electrode impedance is less of a problem. Verify that artifact rejection is OFF.

After data collection, remove the foam eartip, then the TM ECochGtrode. Inspect the ear canal and the tympanic membrane. There may be a small amount of residual electrode gel on the tympanic membrane. The tympanic membrane may be inflamed where the electrode was placed. The gel residue will dry and exude from the ear canal. The tympanic membrane inflammation should abate within a few hours.

1-Channel ECochG with Tiptrode (Horizontal Montage)



3.2.4 Tips for Tiptrodes

The Tiptrode consists of two components: the eartip/electrode and the connector/cable assembly. The electrode is the foam eartip wrapped with gold foil. The connector/cable has an insulated alligator clip for attaching the eartip/electrode to the tubing for transmitting auditory stimuli and an insulated wire to conduct the electrode signal.

Attach the eartip/electrode to the connector. Squeeze the metal clip open and then slide the eartip/electrode on making sure that the alligator clip is touching the gold foil.

Connect the tubing to the output of the insert earphone.

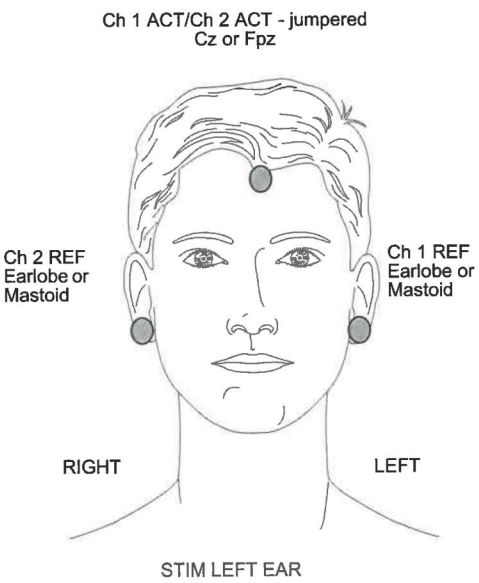
Remove the tubing that is currently on the insert earphone and replace it with the tubing on the Tiptrode. Do NOT double the length of the tubing by attaching the two sets together.

Red tubing goes to the right insert phone and blue tubing to the left insert phone.

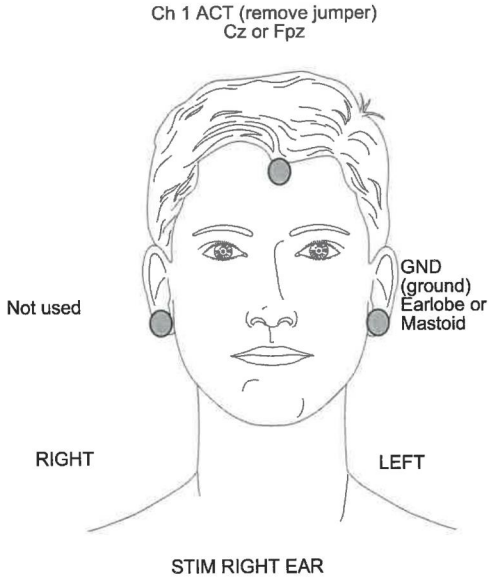
Attach the electrode leadwire to the patient cable. See montages for electrode placement options.

2-CHANNEL ABR with ASSR Following

ABR
2 channel recording



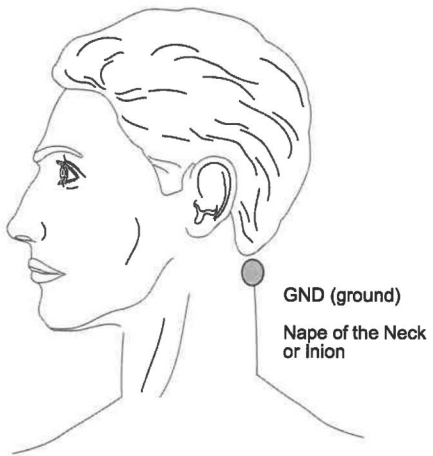
ASSR
(Only a 1 channel recording)



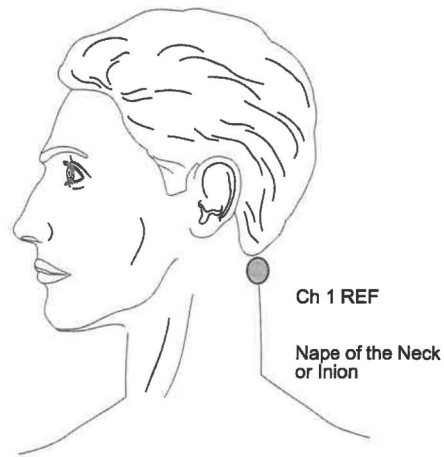
Note · *See* ▶ *35for continuation of this electrode placement.*

2-Channel ABR with ASSR Following (continued)

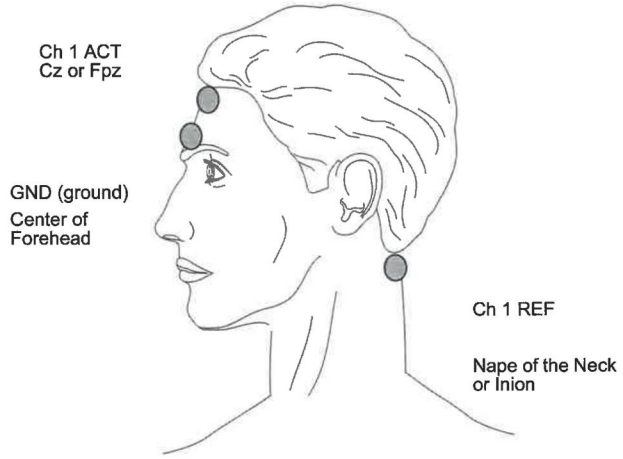
ABR
2 channel recording



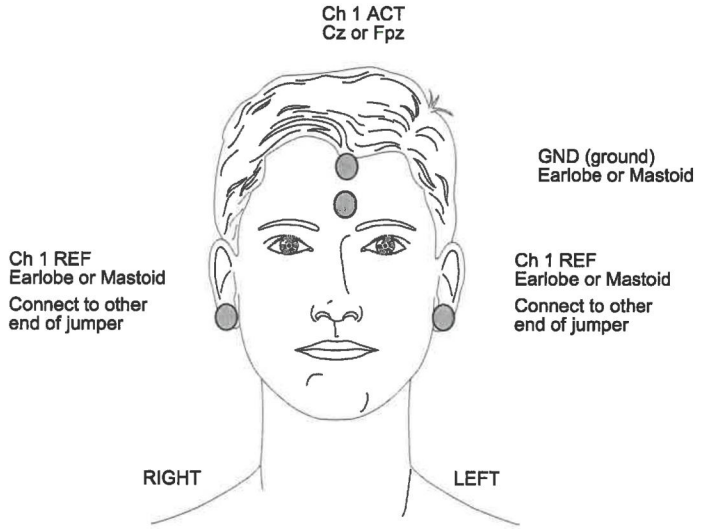
ASSR
(Only a 1 channel recording)



ASSR
(only a 1-channel recording)



ASSR with Linked Mastoids
(only a 1-channel recording)

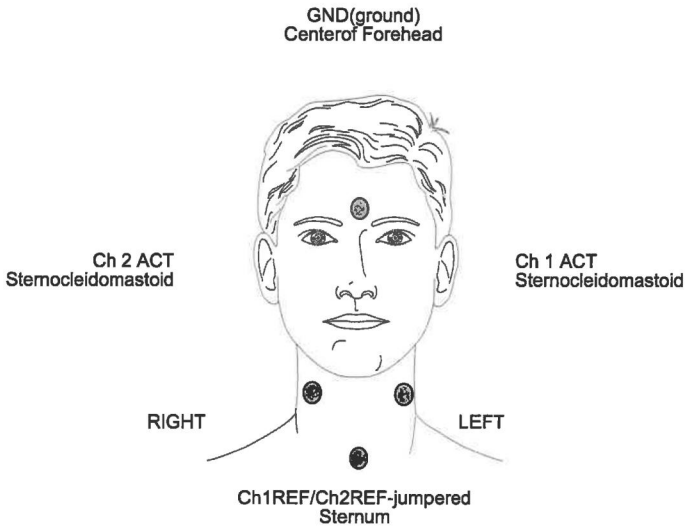


3.2.5 Vestibular Evoked Myogenic Potential (VEMP)

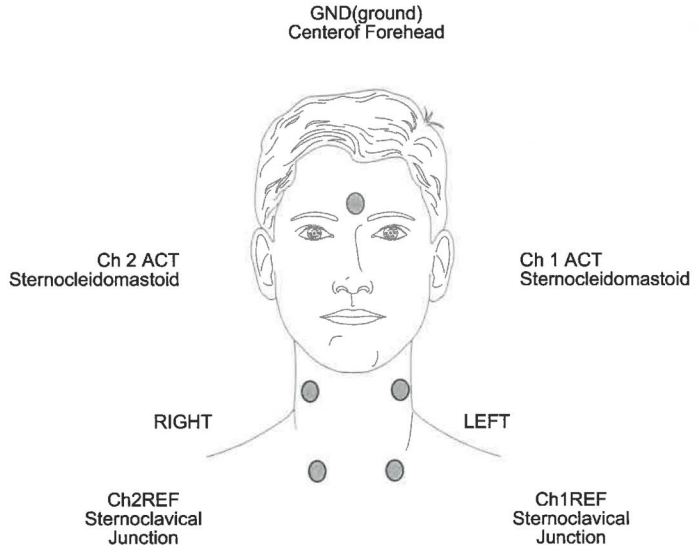
Proper placement of the electrodes on the sternocleidomastoid (SCM) ensures accurate data collection. Have the patient turn his/her head left or right and downward. The SCM should bulge. Place the electrode on the middle and most bulbous part of the SCM. The right and left SCM electrodes should be symmetrical (at the same level) on the patient's neck.

See 3.3 Step 8 VEMP Monitor ▶ 46.

2-Channel VEMP with Sternum Placement
VEMP Monitoring OFF
Binaural or Monaural Stimuli

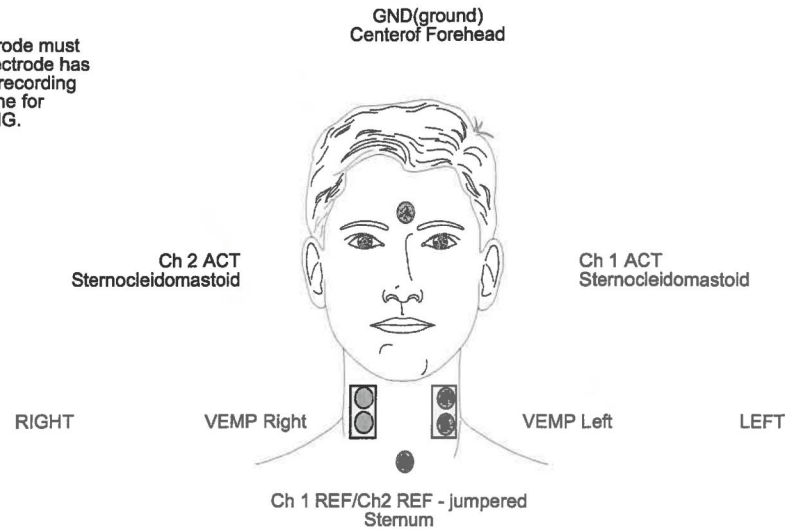


2-Channel VEMP with Sternoclavical Junction Placement
VEMP Monitoring OFF
Binaural or Monaural Stimuli



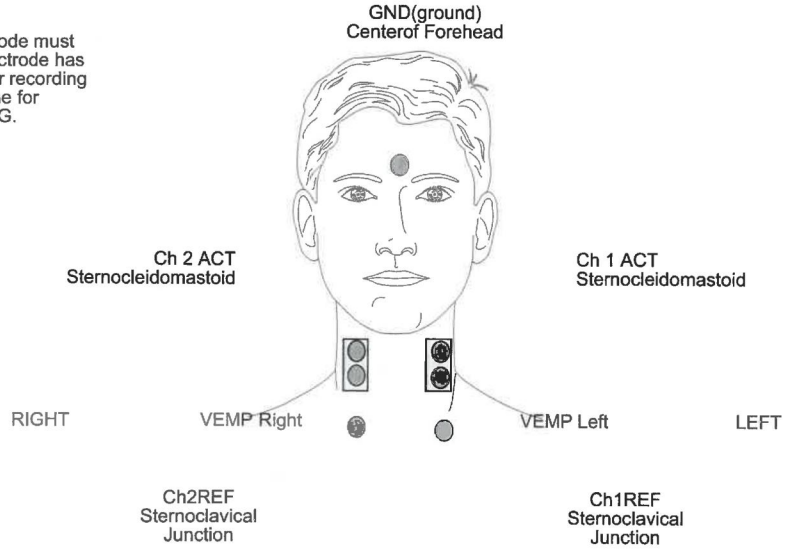
2-Channel VEMP with Sternum Placement
VEMP Monitoring ON
Binaural or Monaural Stimuli

Note:
Differential Electrode must be used. This electrode has 2 leads. One for recording the VEMP and one for recording the EMG.



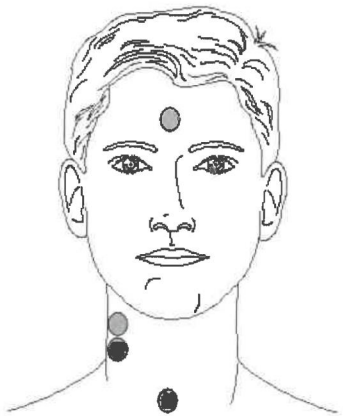
2-Channel VEMP with Sternoclavical Junction Placement
VEMP Monitoring ON
Binaural or Monaural Stimuli

Note:
Differential Electrode must be used. This electrode has two leads. One for recording the VEMP and one for recording the EMG.



1-Channel VEMP-RIGHT
VEMP Monitoring ON

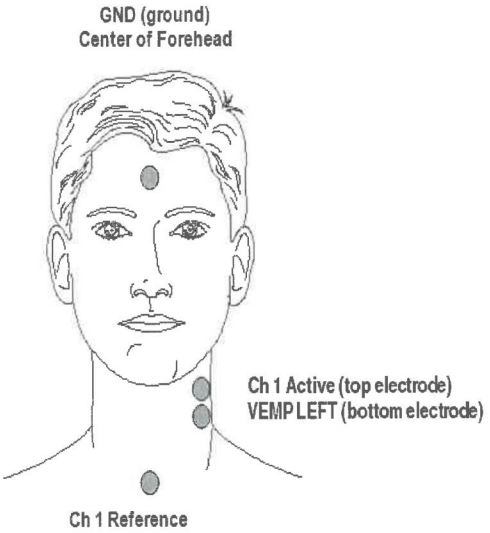
GND (ground)
Center of Forehead
ELECTRODE SWITCHING MUST BE OFF/UNCHECKED



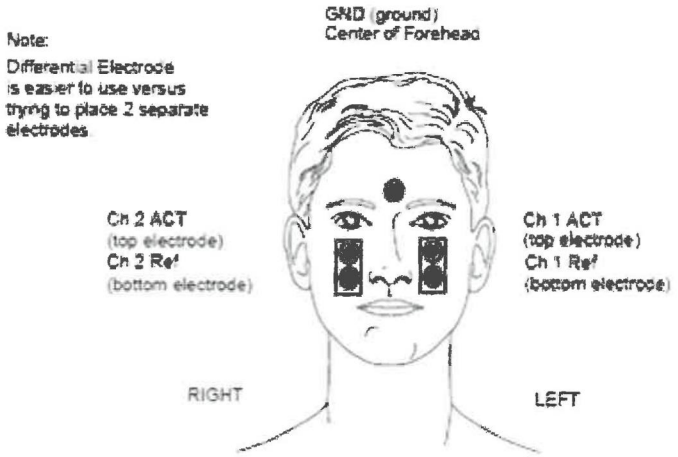
Ch 1 Active (top electrode)
VEMP LEFT (bottom electrode)

Ch 1 Reference

1-Channel VEMP-LEFT
VEMP Monitoring ON



2-Channel OVEMP
VEMP Monitoring OFF
Binaural or Monaural Stimuli



Note · *This montage is not available with the Chartr EP Limited version.*

3.3 Step 8 VEMP Monitor

Why is monitoring tonic EMG activity important?

The sternocleidomastoid must be contracted in order for a response to be recorded. The VEMP is an amplitude measure, and therefore, the influence of the tonic level of the EMG must be taken into account.

"The tonic state of the SCM muscle is a critical parameter in the recording method of the VEMP. Thus, controlling the level of tonic EMG would appear to be a prerequisite for the accurate interpretation of the VEMP." [1]

"The (VEMP) reflex amplitude scales in proportion to tonic EMG activity and should therefore be normalized to the level of EMG activity." [2]

The ICS Chartr EP 200 VEMP MONITOR assesses the level of tonic EMG and displays if the level is adequate or inadequate.

---

[1] Akin FW, Murnane OD, Panus PC et al. (2004) The influence of voluntary tonic EMG level on the vestibular-evoked myogenic potential. J Rehab Res Dev 41(3B):473-480.

[2] Welgampola MS & Colebatch JG (2005) Characteristics and clinical applications of vestibular-evoked myogenic potentials. Neurology 64:1682-1688.

Due to patient variability, it is recommended that the first VEMP run be collected with the EMG values set wide open (e.g., 0 for min and 999 for max). Position the patient to contract the SCM and collect one run. The average EMG will be displayed in the calculation box (bottom left). Then set the min to 20 μV below the average and the max to 20 μV above the average (e.g., if average is 85 μV, then the min = 65 μV and the max = 105 μV).

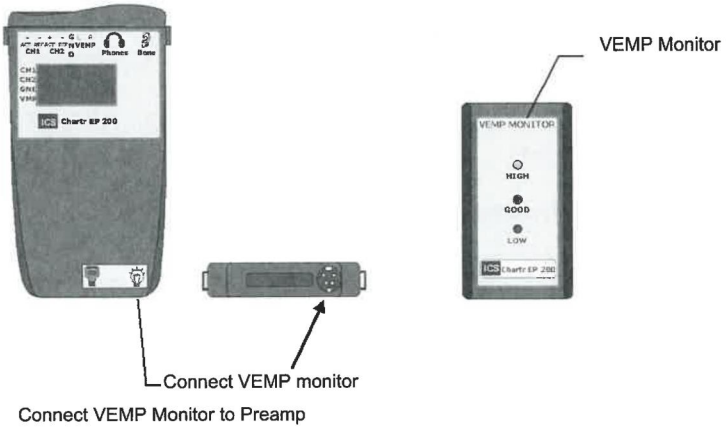
The min and max values should be the same when collecting data from the left and right SCM to ensure that the EMG value is similar on both sides. The response average will only include sweeps when the EMG is in between the min and max values or "Good" range. If the EMG is in the "Low" or "High" range, those sweeps will be rejected.

The monitor light will display the following based on the EMG level:

*Low (blue) – EMG level is below the **Min** value*

*Good (green) – EMG level is between the **Min** value and the **Max** value*

*High (amber) – EMG level is above **Max** value*

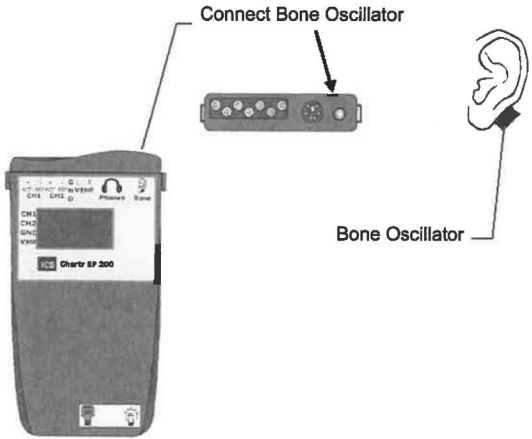


Go to 3.4 Step 9 Connect Bone Conduction Transducer ▶ 48.

3.4 Step 9 Connect Bone Conduction Transducer

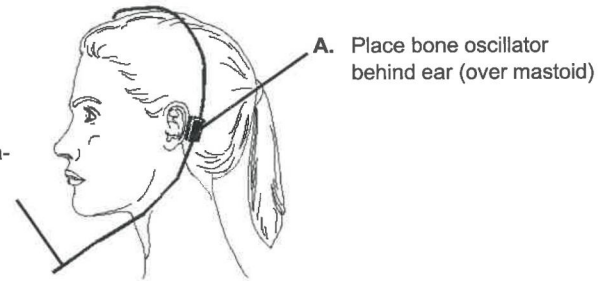
Note · *This step applies only to tests that require bone conduction stimulus.*

1. Connect bone conductor to the Chartr EP (USB) preamplifier.



Connect Bone Oscillator to Preamplifier

2. Place bone oscillator on patient. Place left or right masking insert in ear (optional).



Bone conduction ABR provides a differential diagnosis of the type of hearing loss (sensorineural, conductive, or mixed).

The system default is a 2-channel protocol to be used without masking. The contralateral response will not have a Wave I present and a slightly longer latency for Wave V. Wave I is not always present in the ipsilateral response.

Listening Check

Perform a listening check to verify that the output of the bone oscillator is accurate. See 3.1.5 Listening Check ▶ 22 and 10.5 Establish Normal Hearing Level Thresholds ▶ 125

Electrode Placement

Always use the front of the earlobe when using the bone oscillator. Placing the electrode too close to the bone oscillator causes artifact and noise in the recording.

Bone Oscillator Placement

It is recommended that the bone oscillator be placed on the mastoid. According to ANSI S3.6 1996 using a forehead placement on an adult head can reduce output as much as 15 dB. An infant with a soft spot or fontanel could result in further reduction of output.

Hand-Held Option

Most bone oscillator headbands are too large for infants. A hand-held placement can be used. Firmly hold the oscillator to the infant's mastoid with one finger. Never use two fingers, this can reduce the output. Push the oscillator on the mastoid until you could almost move the patient's head away from you. Make sure the oscillator is not touching the pinna. Transducer placement should be consistent between the sides to reduce variability.

Catheter Holder

Dale Medical Products makes the Foley Catheter Holder (Latex Free) that can be used for holding the bone oscillator in place. It is a 1-inch elastic band. Cut off the strap for the catheter and place Velcro on the back of the bone oscillator. The elastic and Velcro makes it adjustable for any head size. Place the bone oscillator against the mastoid and wrap the strap around the patient's head securing with the Velcro.

Contact:

Dale Medical Products to order
Phone: 800-343-3980
International: 508-695-9316

Website: www.dalemed.com
Product#: H84103161

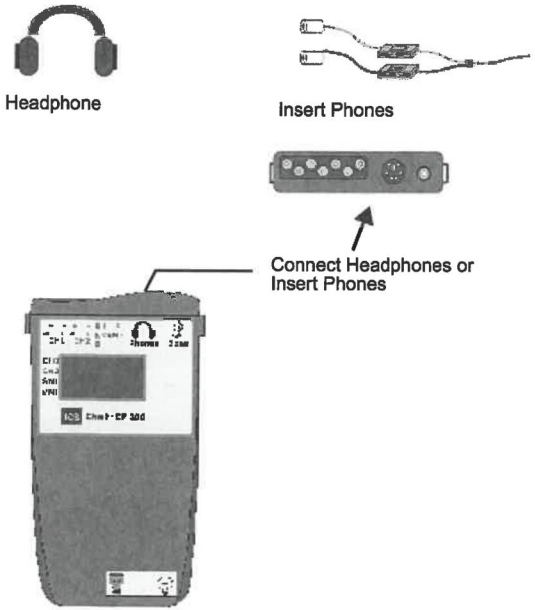
Stimulus Level

Start at a moderate level, 30 dB nHL. Vibration at high intensities from the oscillator can wake a patient. Do not exceed 55 dB nHL, this will overdrive the oscillator and cause stimulus artifact in the recording that could be misinterpreted as a true response.

3. Go to 3.5 Step 10 Connect Insert Earphones ▶ 53.

3.5 Step 10 Connect Insert Earphones

1. Connect the insert earphones or headphones to the Chartr EP (USB) Preamplifier.



Connect Headphones or Insert Phones to Preamp

2. For the insert earphones, place the foam eartips into the patient's ears. Before inserting the foam eartips:

- Perform otoscopic inspection.
- Remove any excess cerumen. Do not irrigate if planning to perform caloric on the same day.
- Instruct the patient regarding what to expect during data collection.

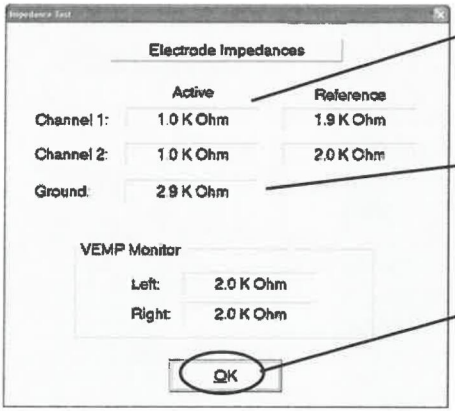
Proper placement of the foam eartips is important. Proper placement ensures that the expected amount of stimulus dB SPL is delivered to the ear. Use the largest eartip that will fit into the patient's ear. Leakage will reduce the amount of dB SPL being delivered to the patient's ear. The eartip should be flush with the outer rim of the ear canal. There should not be foam sitting in the cocha. Maneuver the pinna (up/back for adults, down/back for infants) in order to open the ear canal so that insertion of the foam eartip is easy. Incorrect placement of eartips can result in poor quality recordings and/or increased thresholds.

Double check that the earphones are placed in the correct ears so that test results are not assigned to the wrong ear. Red = Right ear, Blue = Left ear.

3.6 Step 11 Check Electrode Impedance

1. Click F7 Impedance to make sure the electrode connection is good.
2. Read the values for each channel.
   - Make sure there is an impedance reading for each channel with electrodes connected and the ground.
   - Adjust the electrodes as needed.

Impedance readings should be below 5K ohms and within 3K ohms between each other (except for ECochG).



A. Check each active channel and VEMP impedance if using the VEMP monitor.

B. Check the **Ground** (GND).

C. Adjust electrodes, if needed.

D. Click **OK**.

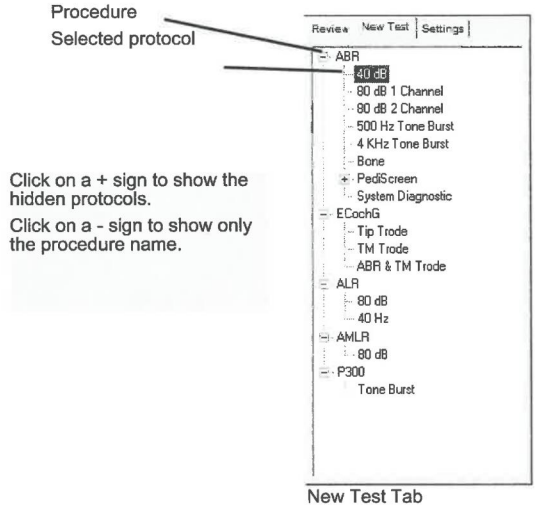
Impedance Test Dialog Box

3. Click **OK** to stop the impedance test.
4. Go to 4.1 Step 12 Select a Protocol ▶ 56.

4 Collect Patient Data

4.1 Step 12 Select a Protocol

1. Click the **New Test** tab on the left side of the Main Window.



New Test Tab

The ICS Chartr EP 200 default (ICS-supplied) procedures are:

ABR (Auditory Brainstem Response)
ECochG (Electrocochleography)
ALR (Auditory Late Response)
AMLR (Auditory Middle Latency Response)
P300

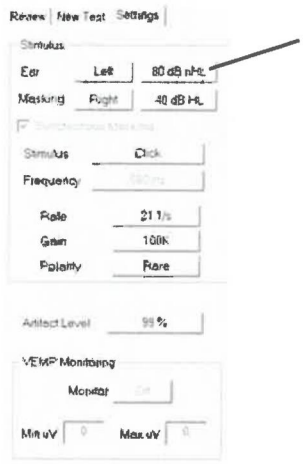
Note · *System Diagnostic is a hardware test, not a protocol. See 7.1 Test Fixture ▶ 90 in the Troubleshooting section of this guide.*

Note · *ECochG, AMLR and P300 protocols are not available in the Chartr EP Limited version. ALR is provided only for 40 Hz. Optional ALR procedures are available.*

2. Click on a protocol to select it.
3. Go to 4.2 Step 13 Adjust Data Collection Settings ▶ 57.

4.2 Step 13 Adjust Data Collection Settings

1. Click on the **Settings** Tab to see the trial settings that will be used for data collection.
2. Review each trial setting parameter.
3. Change the trial settings, if needed.



Settings Tab

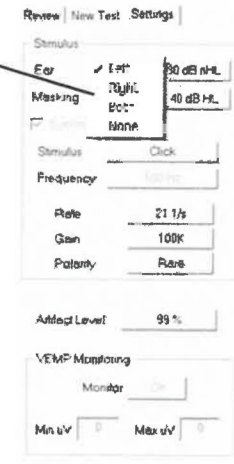
A. Click on a button to see a pop-up menu.

B. Click on an option to select it.

C. Repeat 1 and 2 for each setting you want to modify.

The modified settings are saved with the collected waveforms. They are not available for use with other patients.

Go to 4.4 Step 15 Create, Modify, and Delete Protocols ▶ 59 to modify a trial setting parameter for use on more than one patient.



Settings Tab Pop-up Menu

4. Go to 4.4 Step 15 Create, Modify, and Delete Protocols ▶ 59.

4.3 Step 14 Adjust ASSR Data Collection Settings

This procedure explains how to modify and save ASSR trial settings for use on more than one patient.

1. Select **ASSR > Child Asleep Search** on the **New Test** tab on the Main Menu.
2. Click **F5 Trial Settings** to display the **Edit Protocol - ASSR** dialog.
3. Change the trial setting parameters as needed.

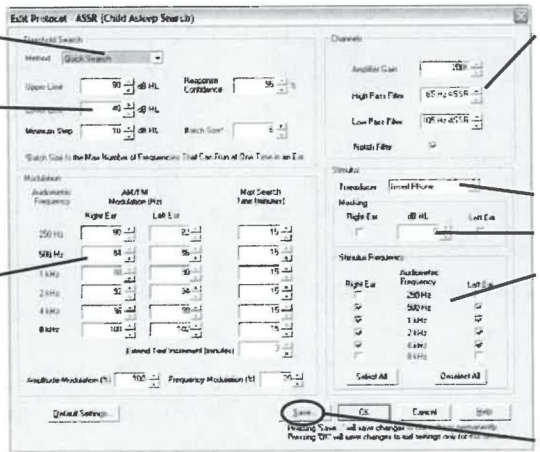
A. Select a method – Quick Search or Straight Descent.

B. Select the Threshold Search options:

- Upper and lower search limits.
- Minimum search step.
- Response confidence.

C. Select the:

- Amplitude (AM)/frequency (FM) modulation for each ear, or AM & FM % for both ears.
- Maximum Search time in



D. Select Channel options:

- Amplifier gain.
- High pass filter.
- Low pass filter.
- Notch filter.

E. Select a transducer.

F. Select a masking level for both ears.

G. Click on a box to select or deselect a frequency.

- Click the **Select All** button to select all frequencies for both ears.
- Click the **Deselect All** button to clear the frequency selections for both ears.

H. Click **Save** to save these settings for all patients.

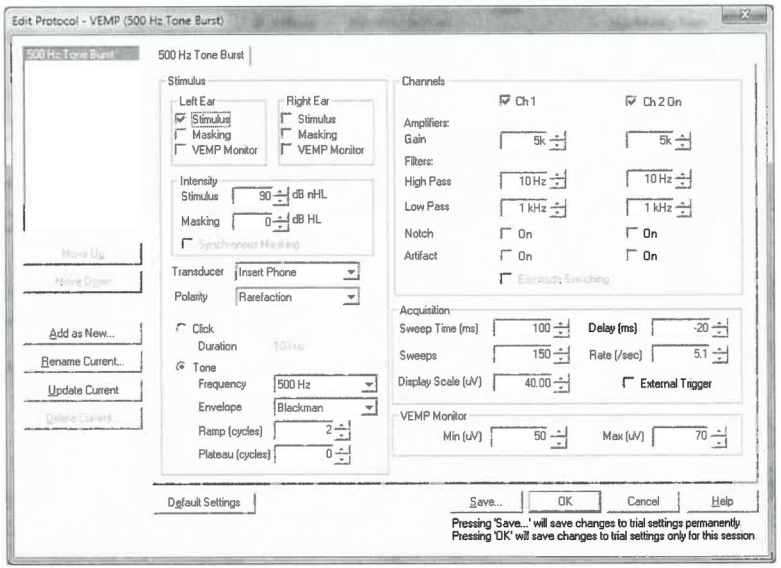
Edit Protocol – ASSR (Quick Search) Dialog box

Note · *Only Channel 1 options are available in the ASSR software.*

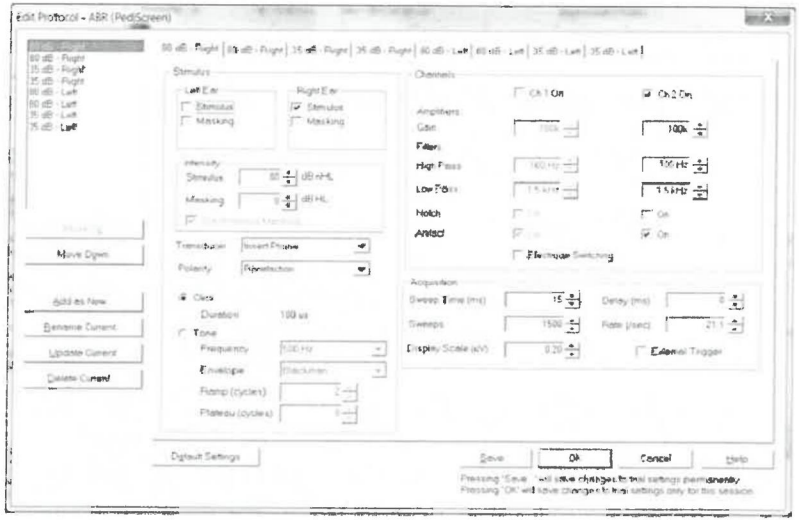
4. Click **Save** to save the modified parameters for the ASSR protocol.
5. Go to 4.4 Step 15 Create, Modify, and Delete Protocols ▶ 59.

4.4 Step 15 Create, Modify, and Delete Protocols

Trial setting parameters may be modified for all EP procedures. In order to create, modify, or delete a protocol, a patient file must be opened. However, these changes will be applicable for all patients.



Single Protocol



Linked (Sequential) Protocol

Save a New Protocol

1. Access the **New Test** tab and highlight the protocol that is most similar to the one to be created
2. Select **Setup > Add New Protocol.**
3. Make modifications to the protocol trial settings.
4. Click **OK.**

5. Choose the Procedure (i.e., ABR, ECochG, VEMP, etc.). The procedure name determines the label set used for marking the waveforms.
6. Change the Protocol Name.
7. Click **OK**. The new protocol will be listed in the New Test tab section under the procedure selected in Step 5 above.

Edit Existing Protocol

1. Access the **New Test** tab and highlight the protocol to be edited.
2. Click **F5 Trial Settings**.
3. Make desired changes.
4. Click **Save**.
5. Click **OK**.

Create a Linked (Sequential) Protocol

1. Access the **New Test** tab and highlight the protocol to be edited.
2. Click **F5 Trial Settings**.
3. Make changes.
4. Click **Add as New**.
5. Change Trial Settings Name.
6. Click **OK**. Protocol will display in the left top panel on the Trial Settings window.

Change Protocol Name

1. Access the **New Test** tab and highlight the protocol to be edited.

2. Click **F5 Trial Settings.**
3. Click **Save.**
4. Change Protocol Name.
5. Click **OK.** The protocol will be listed in the New Test tab with the new name.

Change Name of Test in Linked (Sequential) Protocol

1. Access the **New Test** tab and highlight the protocol to be edited.
2. Click **F5 Trial Settings.**
3. Click **Rename Current.**
4. Change Trial Settings Name.
5. Click **OK.** The protocol will be listed in the left top panel on the Trial Settings window.

Delete Protocol

Note · *Manufacturer default protocols cannot be deleted.*

1. Access the **New Test** tab and highlight a protocol.
2. Select **Setup > Delete Protocol.**
3. Highlight the protocol to be deleted.
4. Click **OK.**
5. Click **Yes** if want to delete the protocol.

Delete test from Linked (Sequential) Protocol

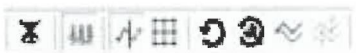
1. Access the **New Test** tab and highlight the protocol to be edited.
2. Click **F5 Trial Settings**.
3. Highlight the protocol to be deleted in the left top panel on the trial settings window.
4. Click **Delete Current**.
5. Click **Yes** if you want to delete the test from the linked protocol.

Reset Default Settings

1. Login as the default operator.
2. Access **New Test** tab and highlight the protocol to be edited.
3. Click **F5 Trial Settings**.
4. Click **Default Settings**.
5. Click **Yes** to reset manufacturer default settings.
6. Go to 4.5 Step 16 Select Data Collection Options ▶ 64.

4.5 Step 16 Select Data Collection Options

1. Click a button on the **Main Window Toolbar** to select one or more of these data collection options.



Right Side of Main Window Toolbar

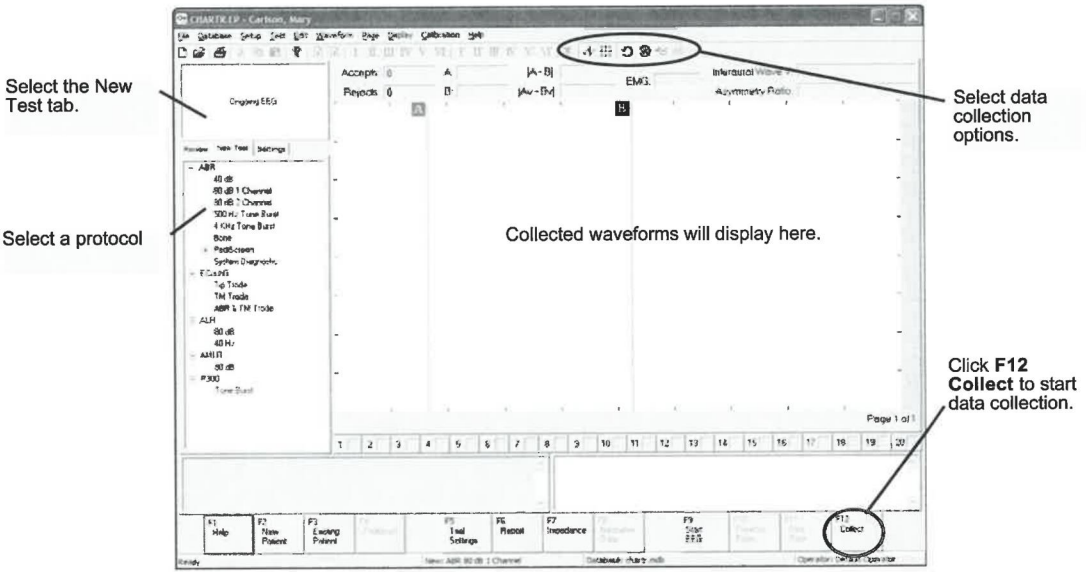
Button	Data Collection Option	Function
	Clear Markers	Click to clear all markers on the selected waveforms.
	Split Screen	Click to split the waveforms such that waveforms with the left ear stimulated are on the left side and waveforms with the right ear stimulated are on the right side.
	Grid	Click to show vertical grid lines.
	Continuous Stimulation	Click to continue the audio tone after a protocol ends. Click again to discontinue the tone. This is ideal for unsedated infants and children.
	Continue Trial	Click to enable data collection (number of sweeps) beyond the set limits. Click again to discontinue the option. Do not use Continue Trial with linked (sequential) protocols.
	Merge New Waveform	Click to merge waveforms automatically at the beginning of a trial. Merge will sort and order the waveforms on a page based on the ear stimulated, the collection channel, the stimulus intensity, and the tone frequency.
	Interaural Wave V	Click to show the latency difference between Wave V of a left waveform and right waveform. Waveforms selected must be collected using an ABR click protocol and must have Wave V marked.

2. Go to 4.6 Step 17 Start Data Collection ▶ 66.

4.6 Step 17 Start Data Collection

All data collection activities are controlled and monitored from the Main Window.

1. Click **F12 Collect** to begin data collection.


Select the New Test tab.
Select a protocol
Collected waveforms will display here.
Select data collection options.
Click F12 Collect to start data collection.

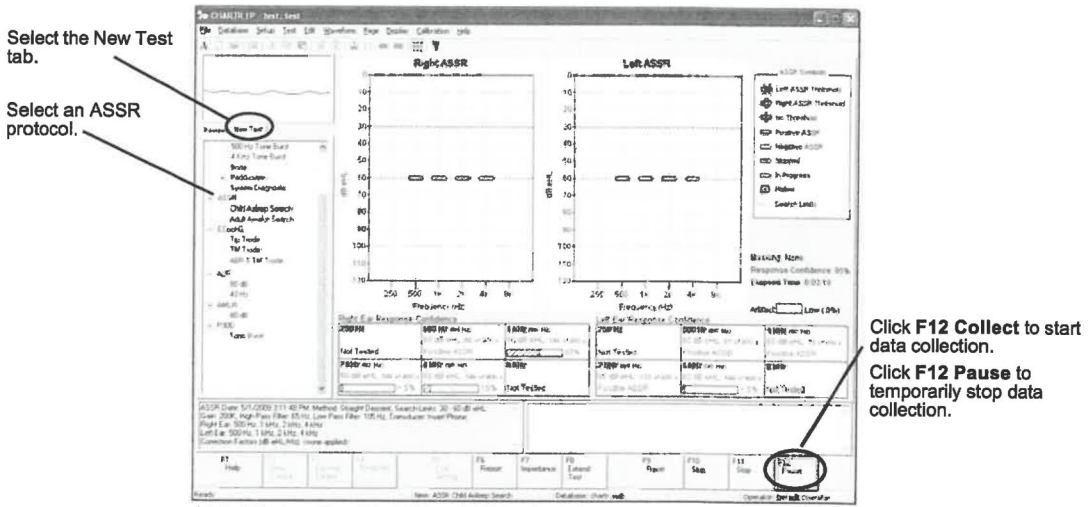
Main Window, New Test Tab

2. Go to 4.8 Step 19 Monitor Data Collection ▶ 68.

4.7 Step 18 Start ASSR Data Collection

All data collection activities are controlled and monitored from the Main Window.

1. Click **F12 Collect** to begin data collection.

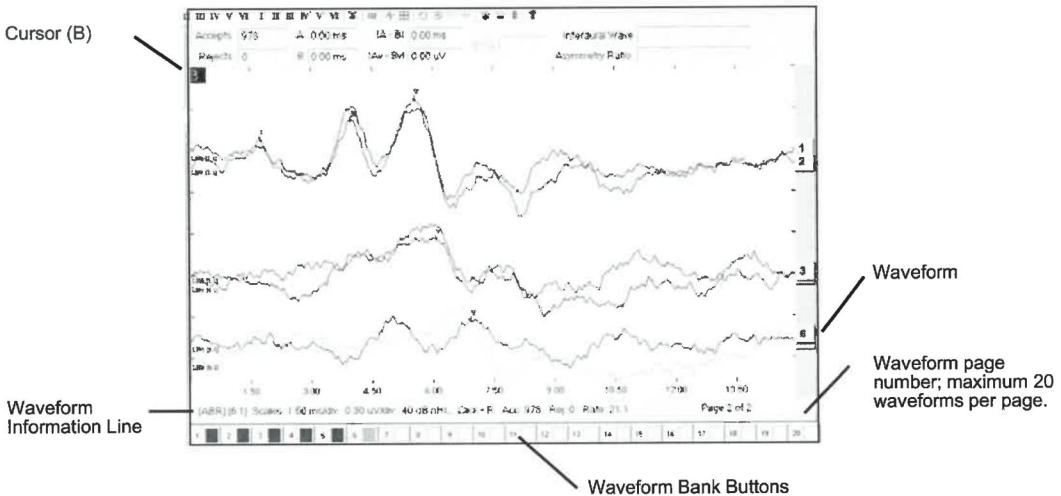

Select the New Test tab.
Select an ASSR protocol.
Right ASSR
Left ASSR
Click **F12 Collect** to start data collection.
Click **F12 Pause** to temporarily stop data collection.

Main Window, New Test Tab – ASSR selected

2. Go to 4.8 Step 19 Monitor Data Collection ▶ 68.

4.8 Step 19 Monitor Data Collection

1. Monitor data collection.



Waveform Work Area

2. Use the Function keys to adjust data collection options. (Note: gray = not currently active)

Function Keys, During Data Collection

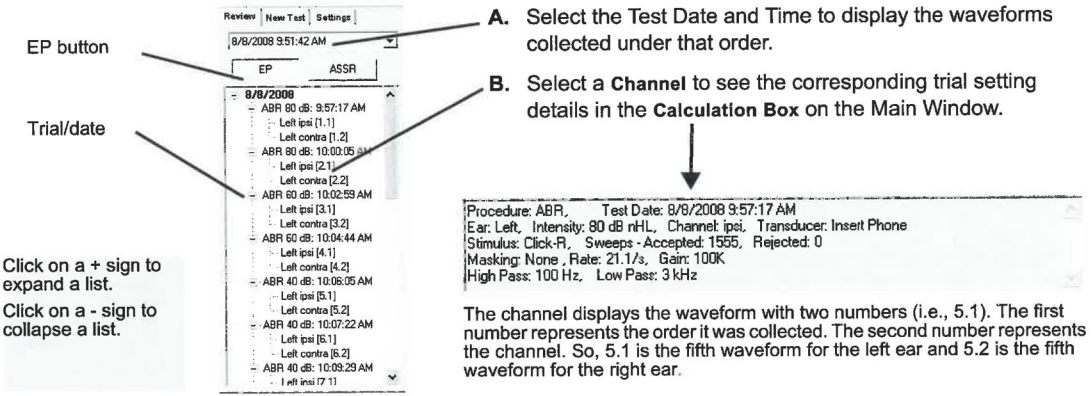
F1 Help	Display User Manual.	**F9 Reset**	Stop the trial, delete the current or the last completed trial, and reset the sweep counter to zero.
F4 PediGram	Display PediGram data.	**F10 Increase Sweeps**	Increase maximum sweeps for the current trial.
F6 Report	Display Patient Report.	**F11 Stop**	Stop the current trial.
F8 Normative Data	See normative data graphs for selected waveform. To select all waveforms, click Ctrl+ A.	**F12 Pause/Resume**	Pause the current trial. Resume current trial.

3. Go to 5.1 Step 20 EP Review Tab ▶ 70.

5 Review Collected Data

5.1 Step 20 EP Review Tab

1. Click the **Review** tab on the left side of the Main Window.
2. Click the **EP** Button to review all results.
3. Click on a channel to display the collected waveform.

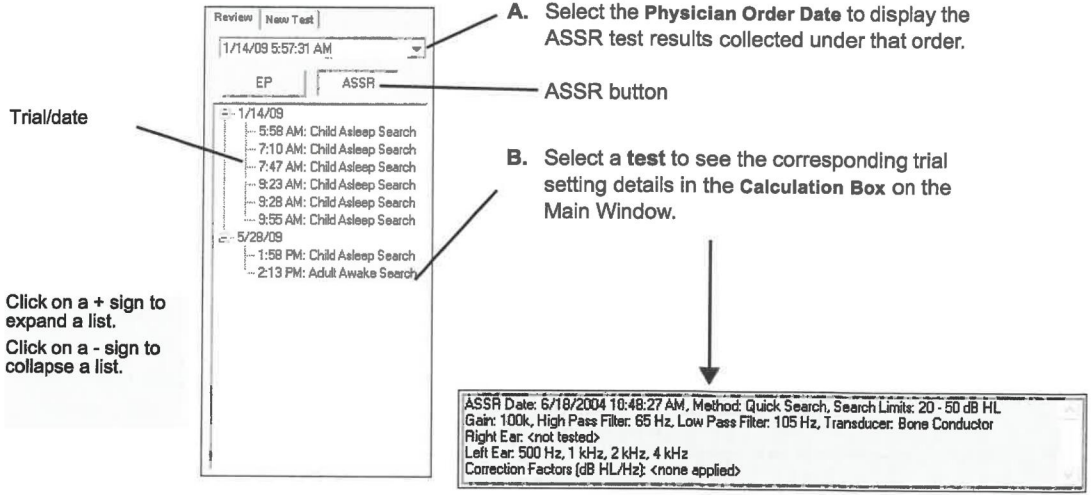

EP button
Trial/date
Click on a + sign to expand a list.
Click on a - sign to collapse a list.
Review
New Test
Settings
8/8/2008 9:51:42 AM
EP
ASSR
8/8/2008
ABR 80 dB: 9:57:17 AM
Left ipsi [1.1]
Left contra [1.2]
ABR 80 dB: 10:02:05 AM
Left ipsi [2.1]
Left contra [2.2]
ABR 60 dB: 10:02:59 AM
Left ipsi [3.1]
Left contra [3.2]
ABR 60 dB: 10:04:44 AM
Left ipsi [4.1]
Left contra [4.2]
ABR 40 dB: 10:06:05 AM
Left ipsi [5.1]
Left contra [5.2]
ABR 40 dB: 10:07:22 AM
Left ipsi [6.1]
Left contra [6.2]
ABR 40 dB: 10:09:29 AM
A. Select the Test Date and Time to display the waveforms collected under that order.
B. Select a Channel to see the corresponding trial setting details in the Calculation Box on the Main Window.
Procedure: ABR, Test Date: 8/8/2008 9:57:17 AM
Ear: Left, Intensity: 80 dB nHL, Channel: ipsi, Transducer: Insert Phone
Stimulus: Click-R, Sweeps - Accepted: 1555, Rejected: 0
Masking: None , Rate: 21.1/s, Gain: 100K
High Pass: 100 Hz, Low Pass: 3 kHz
The channel displays the waveform with two numbers (i.e., 5.1). The first number represents the order it was collected. The second number represents the channel. So, 5.1 is the fifth waveform for the left ear and 5.2 is the fifth waveform for the right ear.

Review Tab - EP

4. Go to 5.3 Step 22 Work with Waveforms ▶ 72.

5.2 Step 21 ASSR Review Tab

1. Click the **Review** tab on the left side of the Main Window.
2. Click the **ASSR** button to display the ASSR results.

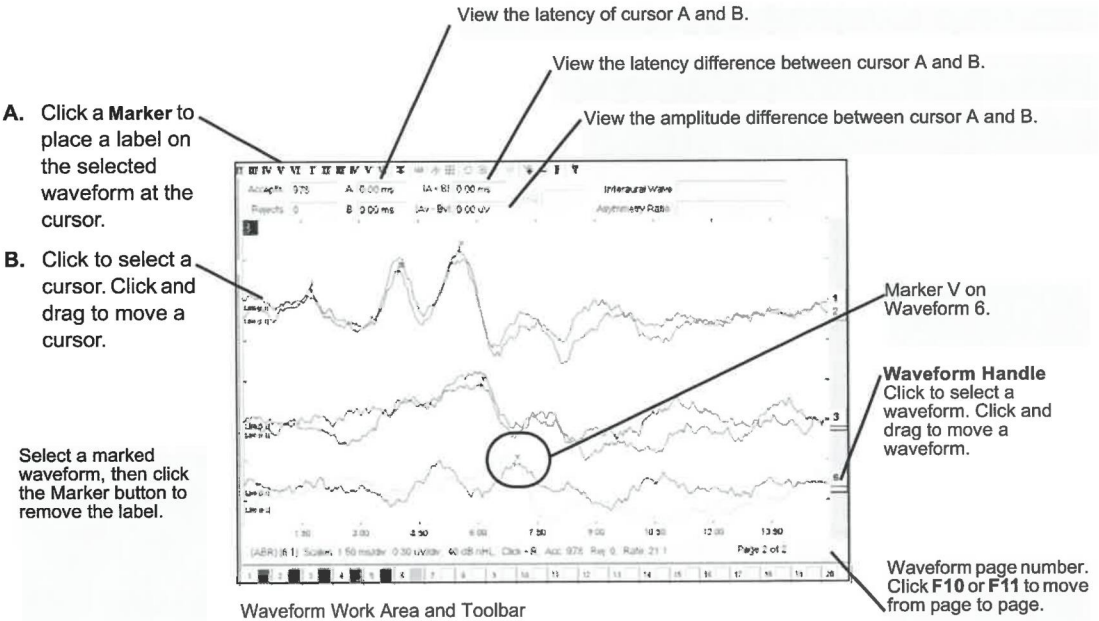

Review
New Test
1/14/09 5:57:31 AM
EP
ASSR
1/14/09
5:58 AM: Child Asleep Search
7:10 AM: Child Asleep Search
7:47 AM: Child Asleep Search
9:23 AM: Child Asleep Search
9:28 AM: Child Asleep Search
9:55 AM: Child Asleep Search
5/28/09
1:58 PM: Child Asleep Search
2:13 PM: Adult Awake Search
A. Select the Physician Order Date to display the ASSR test results collected under that order.
ASSR button
Trial/date
B. Select a test to see the corresponding trial setting details in the Calculation Box on the Main Window.
Click on a + sign to expand a list.
Click on a - sign to collapse a list.
ASSR Date: 6/18/2004 10:48:27 AM, Method: Quick Search, Search Limits: 20 - 50 dB HL
Gain: 100k, High Pass Filter: 65 Hz, Low Pass Filter: 105 Hz, Transducer: Bone Conductor
Right Ear: <not tested>
Left Ear: 500 Hz, 1 kHz, 2 kHz, 4 kHz
Correction Factors (dB HL/Hz): <none applied>

Review Tab – ASSR

3. Go to 5.3 Step 22 Work with Waveforms ▶ 72.

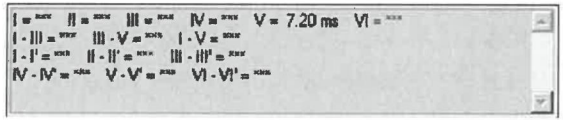
5.3 Step 22 Work with Waveforms

1. Move the waveforms on a page.
2. Place **Marker Labels** on selected waveforms.

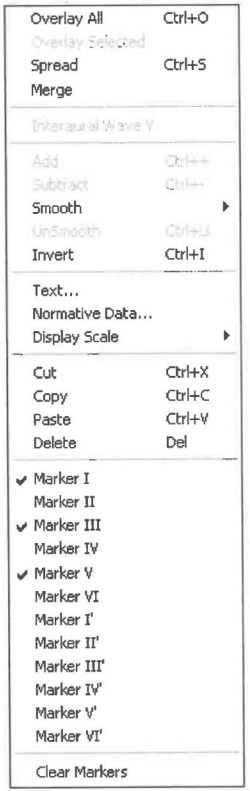

View the latency of cursor A and B.
View the latency difference between cursor A and B.
View the amplitude difference between cursor A and B.
A. Click a **Marker** to place a label on the selected waveform at the cursor.
B. Click to select a cursor. Click and drag to move a cursor.
Select a marked waveform, then click the Marker button to remove the label.
Marker V on Waveform 6.
Waveform Handle Click to select a waveform. Click and drag to move a waveform.
Waveform page number. Click **F10** or **F11** to move from page to page.

Waveform Work Area and Toolbar

3. Check the **Calculation Box** on the Main Window to see the marked latency and amplitude for the selected, marked waveform (Example: waveform 6 with Marker V data).



4. Use the **Waveform Pop-up Menu** to manipulate waveforms:
   - Select one or more waveforms (press and hold Ctrl then click on each desired waveform).
   - Place the cursor over the Waveform Work Area and right-click the mouse button to display the Waveform Pop-up Menu.



Waveform Pop-up Menu

Menu Option	Function
Overlay All	Superimpose all the waveforms. Press **Ctrl + O** to overlay all the waveforms on a page.
Overlay Selected	Superimpose two or more selected waveforms.
Spread	Distribute all of the waveforms on the page at equal intervals. Press **Ctrl + S** to spread all the waveforms on a page.
Merge	Display waveforms with similar collection parameters together.
Interaural Wave V	Display the difference in the latency of Wave V for a left and right ABR click waveform.
Add	Add selected waveforms on a page. The added waveform represents the weighted average of the component waveforms. The resulting waveform will be placed in the first unused waveform bank on the page. Press **Ctrl + +** to add selected waveforms.
Subtract	Subtract one waveform from another. The resulting waveform will be placed in the first unused waveform bank on the page. Press **Ctrl + -** to subtract selected waveforms.
Smooth	Smooth one or more waveforms at a time. Select the amount of smoothing (7 to 23 points) that will be applied.
Menu Options	Function
Unsmooth	Remove smoothing from selected waveforms. Press **Ctrl + U** to remove smoothing from selected waveforms.
Invert	Invert the selected waveforms. Press **Ctrl + I** to invert selected waveforms.
Text	Allows users to provide comment per waveform.

Menu Option	Function
Normative Data	Display normative data for click and toneburst.
Display Scale	Modify the display scale of the selected waveform.
Cut	Remove selected waveforms and save on the clipboard.
Copy	Copy the selected waveforms to the clipboard.
Paste	Insert waveforms from the clipboard.
Delete	Remove selected waveforms.
Markers	Add the selected marker at the site of the active cursor.
Clear Markers	Remove all markers on selected waveform(s).

5. Go to 5.4 Step 23 View Data Graphs ▶ 75.

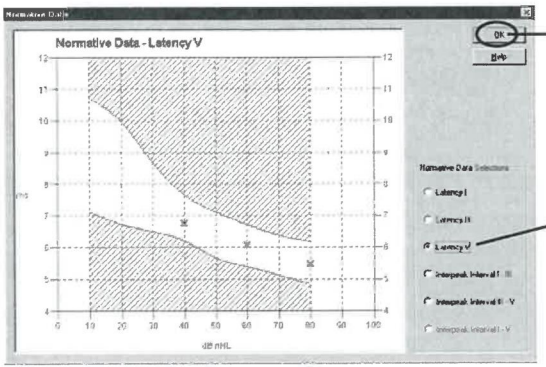
5.4 Step 23 View Data Graphs

5.4.1 Click Normative Data

Normative Data for Latencies I, III, and V and for Interpeak Intervals I-III, III-V, and I-V can be viewed and printed as part of the patient report. To view these data, select at least one ABR or one ECochG waveform with marker labels or to view all waveforms click Ctrl + A. The waveform's stim-

ulus intensity must be in the normative data range and normative data for the current patient's age must be available. On the graphs, data points are indicated by the ear stimulated (x = left; • = right).

1. Place the appropriate markers on selected click waveform(s). (See 4.8 Step 19 Monitor Data Collection ▶ 68.)
2. Select the marked waveform(s) and click **F8 Normative Data** to display the **Normative Data** dialog box.



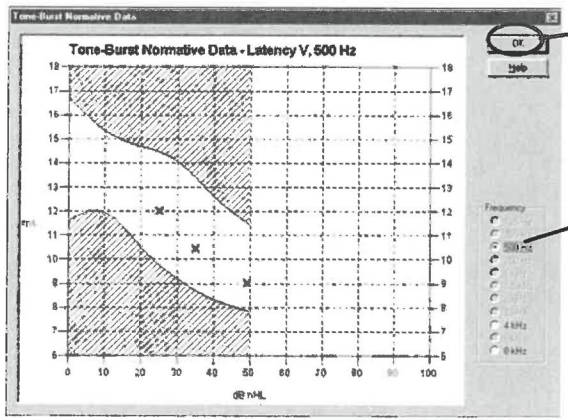
Normative Data Dialog Box

3. Click **OK** to close the dialog box.

5.4.2 Tone-Burst Normative Data

Tone-Burst Normative Data graphs compare Latency V data against normative data. The waveform's stimulus intensity must be in the normative data range and normative data for the current patient's age must be available.

1. Place the appropriate markers on selected tone-burst waveform(s). (See 4.8 Step 19 Monitor Data Collection ▶ 68)
2. Select the marked waveform(s), then select **F8 Normative Data** to display the **Tone Burst Normative Data** dialog box.



D. Click **OK**.

A. Click on a frequency to view the corresponding data graph.

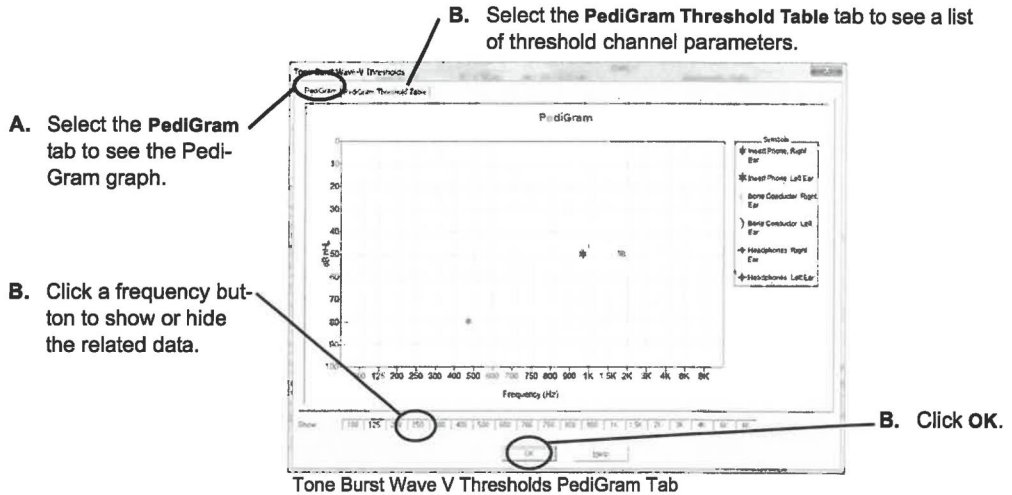
Tone-Burst Normative Data Dialog

3. Click **OK** to close the dialog.

5.4.3 PediGram Data

The PediGram graph shows the estimated hearing level threshold (dB nHL) by ear for each tone burst frequency. The vertical bars highlight typical frequencies tested. Thresholds are determined by the ABR waveform with both the lowest stimulus intensity and a Marker V label. The PediGram Threshold Table provides a list of parameters for all channel data used as thresholds on the PediGram.

1. Select **F4 > PediGram** to display the **Tone-Burst Wave V Thresholds** dialog box.


B. Select the PediGram Threshold Table tab to see a list of threshold channel parameters.
A. Select the PediGram tab to see the Pedi-Gram graph.
B. Click a frequency button to show or hide the related data.
B. Click OK.
PediGram
Frequency (Hz)
Tone Burst Wave V Thresholds PediGram Tab

2. Click **OK** to close the dialog box.
3. Go to 5.4 Step 23 View Data Graphs ▶ 75.

6 Print a Patient Report

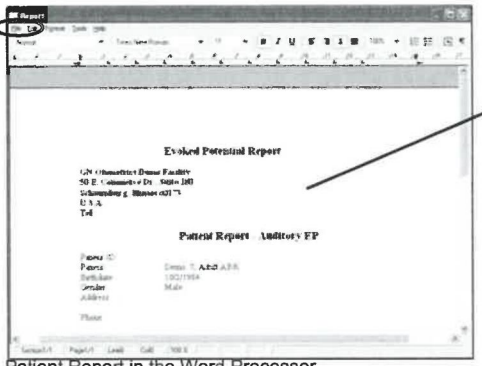
6.1 Step 24 Prepare Report

Patient reports consist of patient information and graphic representations of test results. The operator selects the test results that will be included in the report and may edit the patient and system information in the word processor. Reports may be saved and printed.

1. Click **F6 Report** on the Main Window to open the report in the word processor.
2. Review the report and edit the information if needed.

Click **File** and select **Print EP Report** to print the word processor report, waveforms, and normative data.

Click **File** and select **Save** to save the changes and return to the Main Window.



Place the cursor in the report and make changes as needed.

Patient Report in the Word Processor

3. Select **File > Save** on the Menu bar.
4. Click **File > Print EP Report** to print the word processor report, waveforms, and normative data.
5. Go to 6.2 Step 25 Creating Macros ▶ 81.

6.2 Step 25 Creating Macros

Macros are defined wording that can be added to the report. Creating a macro allows you to set up typically used summaries of findings that can be easily pulled into a report. By creating macros, you can reduce the amount of time typing in the findings for each individual patient.

Macros can be edited and/or expanded upon once entered into the report.

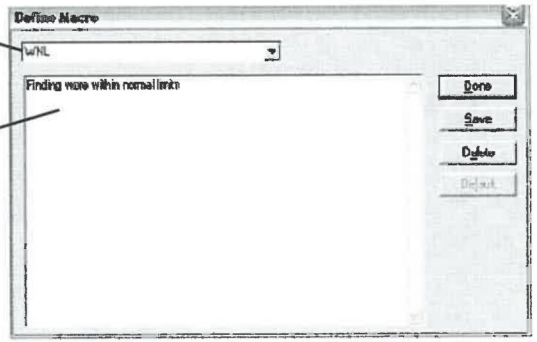
Set up a Macro

1. Click **F6 Report.**
2. Click on **Tools** (in the menu bar).

3. Click **Define Macro.**

   A. Type the Macro name (i.e., WNL). If using a Chartr VNG/ENG system, add the test type to the name (i.e., WNL-EP).

   B. Type the text.



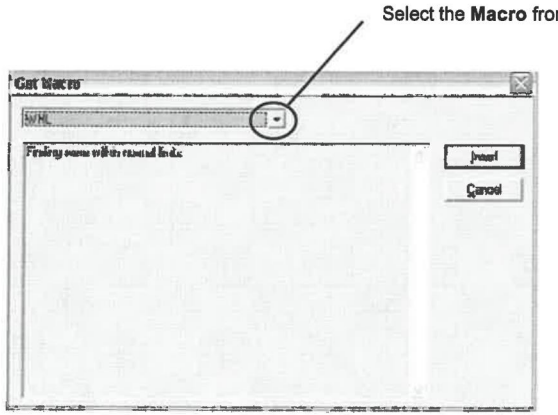
Define Macro Dialog Box

4. Click **Save.**
5. Click **Done.**

Insert the Macro into a Report

1. Click **F6 Report.**
2. Place cursor in the report where you want the macro to be placed.
3. Click on **Tools** (in the menu bar).

4. Click **Get Macro.**



Get Macro dialog box

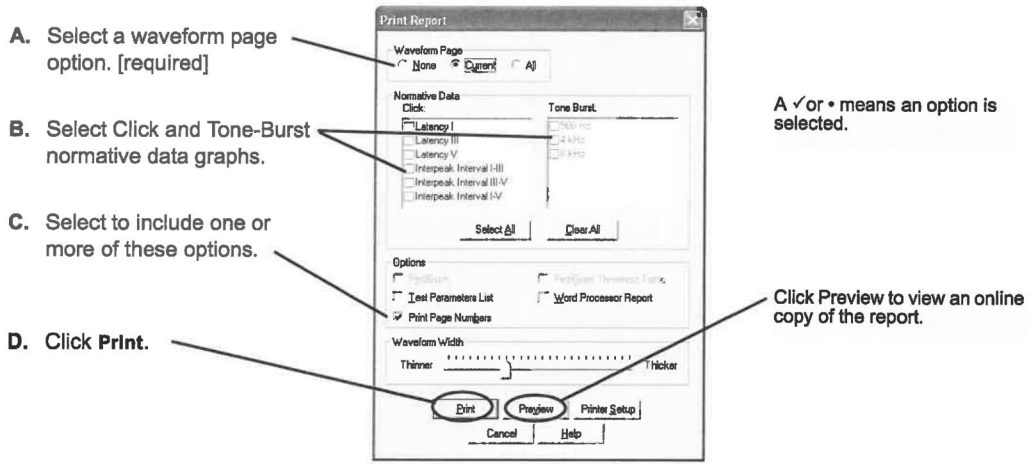
5. Select the **Macro** from drop down.
6. Click **Insert.**
7. Edit the text in the report if needed.

6.3 Step 26 Print EP Report

Use the Print Report dialog box to select the information (patient data and/or test results) that will be included in a printed report. Reports are printed on Letter or A4 size paper.

1. Select **File > Print EP Report** on the Main Window Menu bar or from the Word Processing Report to display the **Print Report** dialog box.
2. Select the items you want to include in the report

.



Print Report Dialog Box

3. Click **Print** to send the report to the printer.

6.4 Step 27 Print an ASSR Report

1. Select **File > Print ASSR Report** on the Main Window Menu bar or from the Word Processing Report to display the **ASSR Print Report** dialog box.

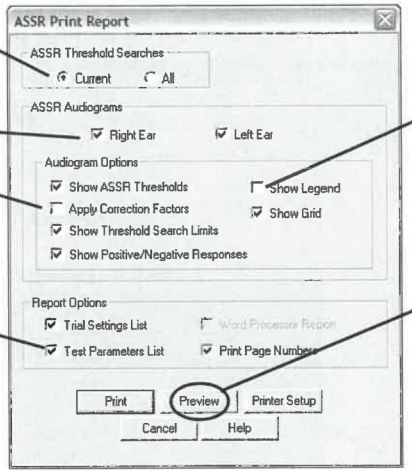
2. Select report options.

A. Select to include only current search results or all search results.

B. Select to include left and/ or right ear data.

C. Select to include one or more of these options in the report.

D. Select to include these optional items in the report.



ASSR Print Report Dialog Box

E. Select to include the ASSR symbol legend in the report.

Click **Preview** to view an online copy of the report.

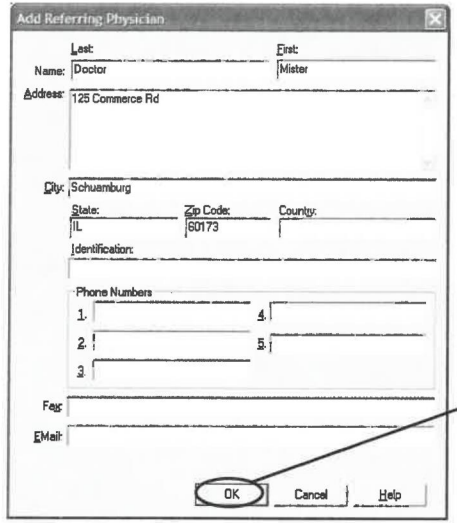
A ✓or • means an option is selected.

3. Click **Print** to send the report to the printer.

6.5 Step 28 Set up Referring Physician Records

1. Select **Setup > Add New Referring Physician** on the Menu bar to display the **Add Referring Physician** dialog box.

2. Type the requested information.



Add Referring Physician Dialog Box

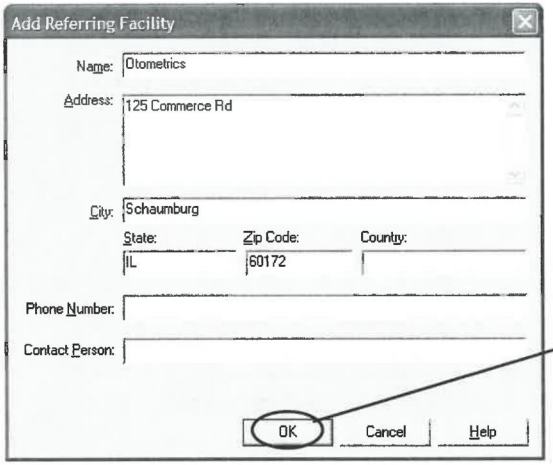
A. Type this information:
- Name (last, first) [required]
- Address
- City
- State, Zip Code, Country
- Identification
- Telephone Numbers (up to 5)
- Fax number
- EMail address

B. Click **OK**.

3. Click **OK** to create a new referring physician record.
4. Go to 2.5 Step 5 Select Referring Physician and Facility ▶ 17.

6.6 Step 29 Set up New Referring Facility

1. Select **Setup > Add New Referring Facility** on the Menu bar to display the **Add Referring Facility** dialog box.
2. Type the requested information.



Add Referring Facility Dialog Box

A. Type this information:
- Name of the facility [required]
- Address
- City
- State, Zip Code, Country
- Telephone Number
- Contact Person

B. Click **OK**.

3. Click **OK** to create a new referring facility record.
4. Go to 2.5 Step 5 Select Referring Physician and Facility ▶ 17.

7 Maintenance and Troubleshooting

The troubleshooting information in this section includes:

- **Test Fixture**
  A method for testing the status of the auditory stimulus and the data collection portions of the ICS Chartr EP 200 hardware.
- **Cleaning and Maintenance**
- **Fuse Replacement**
  Instructions for replacing the Powertronix Isolation Station.
- **Archiving Database**
  Instructions for archiving the patient database.
- **Database Repair Utility**
  A method for attempting to fix a corrupt database.

See Section 9 of the *ICS Chartr EP User Manual* for additional troubleshooting information.

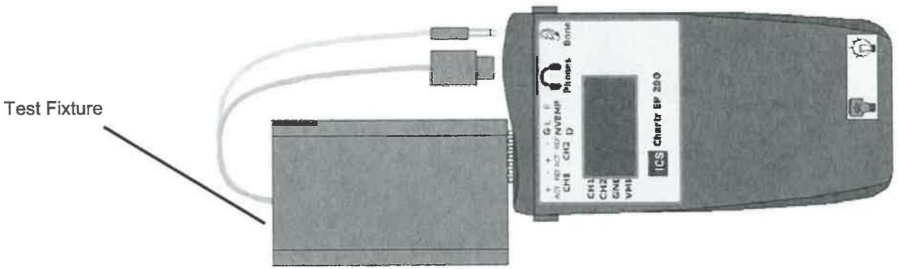
Note · *Special Notice*

Service and repair of electro-medical equipment should only be done by the equipment manufacturer or by authorized representatives. The manufacturer reserves the right to disclaim all responsibility for the operating, safety, reliability, and performance of equipment serviced or repaired by other parties.

7.1 Test Fixture

The Test Fixture checks the working condition of the auditory stimulus and data collection portions of the Chartr EP 200 hardware.

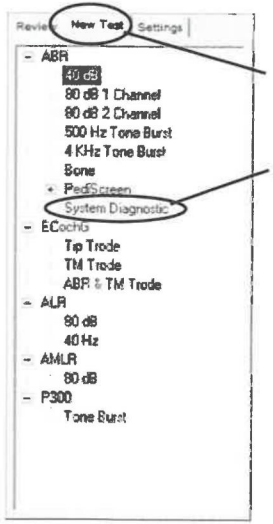
1. Make sure the PC is turned off, and then make these cable connections:
   - Unplug the electrodes, Earphone cable (labeled Phone), and the bone oscillator (labeled Bone) from the Chartr EP (USB) preamp and plug in the Test Fixture cable.
   - Plug the Test Fixture into the electrode jacks of the preamp and the transducer connector.



Plug Test Fixture into Preamp

2. Turn on the PC and double-click (ICS Chartr EP icon) to display the Operator Login window.
3. Select an Operator and click **OK** to display the Main Window.

4. Select **File > New Patient** to start a patient record. Type a Patient name and Birthdate, then click **OK** to return to the Main Window. (See 2.4 Step 4 Set up Patient Record ▶ 16.)
5. Click the **New Test** tab and select the **ABR: System Diagnostic** protocol.
6. Click **F12 Collect** function key to run the test.
7. Check the results:
   - If the test did not produce a noise-free sinusoid, contact GN Otometrics.
   - If the test produced a noise-free sinusoid, select **File > Delete Patient**, click on the patient record you created in step 4, and click **OK** to delete the record.
8. Return the equipment to operating status by closing ICS Chartr EP and turning off the PC.
9. Unplug the test fixture from the Preamp and reconnect electrodes, earphones, and bone oscillator.
10. Remove the Patient Electrode cable from the Test Fixture.



New Test Tab

Note · *ECochG, AMLR and P300 protocols are not available in the Chartr EP Limited version. ALR is provided only for 40 Hz. Optional ALR procedures are available.*

11. Turn on the PC and double-click (ICS Chartr EP icon) to start an EP work session.

7.2 Cleaning and Maintenance

ICS Chartr EP 200 equipment does not require preventive maintenance. However, observe the following recommended guidelines.

Keep the instrument clean and as free of dust as possible. Remove dust using a soft cloth or brush.

To clean, use a soft, slightly damp cloth with a small amount of mild detergent. **Do not allow any moisture to get inside the instrument.**

7.3 Fuse Replacement

Fuses are in a fuse holder assembly that is part of the power entry module on the rear panel of the Powertronix Isolation Station. To access the fuses, remove the fuse holder assembly from the power entry module.

Note · ***Important***
Replace failed fuses only with fuses identified by the fuse rating label located on the unit next to the power entry module assembly.

1. Locate the power entry module on the rear panel of the Isolation Station and find the fuse holder assembly.

2. Remove the line cord and note the voltage indicated on the fuse holder assembly.
3. Use a flat-blade screwdriver to remove the fuse holder assembly from the power entry module.
4. Expose the fuse by carefully prying up on the small clip that is molded into the holder assembly and sliding the fuse block out of the holder.
5. Replace the failed fuses. Use slo-blo fuses.
   - For 115Vac systems use 250V 5A fuses (5 x 20 mm)
   - For 230Vac systems use 250V 3.15A fuses (5 x 20 mm)
6. Slide the fuse block into the holder assembly while making sure the clip "latches" the fuse block assembly.
7. Reinstall the fuse holder assembly into the power entry module. Check that the proper voltage is displayed.
8. Reconnect the line cord to the power entry module.

7.4 Archiving Database

The database should be archived every 50 patients. When the database is archived, a new empty database is created. We recommend saving your archived database to an external medium (CD-ROM, DVD, etc.).

Note · *Data that has been archived CANNOT be added to or reanalyzed and saved.*

Archive a database

1. Close any open patient records.
2. Click **File.**
3. Click **Database.**
4. Click **Archive** and **Start New Database.**
5. Select the location (in "Look in:" box) where the archived database will be stored. The name will include the date the data was archived.
6. Click **Open**

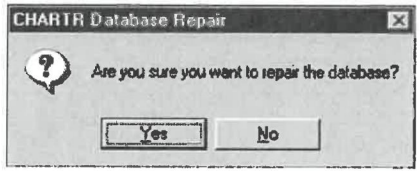
View archived data

1. Close any open patient records.
2. Click **File.**
3. Click **Database.**
4. Click **View Archived Database.**
5. Click on the Database you want to open, and click **Open.**

7.5 Database Repair Utility

Use the Database Repair Utility to attempt to fix a corrupt database. Use this utility only if a message prompt, indicating the database is corrupt, displays when an operator is trying to access or save information.

1. Make sure ICS Chartr EP is closed.
2. Click Start on the Taskbar and select **Programs > GN Otometrics > Chartr Database Repair** to display this prompt.
3. Click **Yes** to repair the database.



The utility will close automatically when the process is done.

If you click **No**, the utility will not start.

Database Repair Utility Prompt

4. Double-click (ICS Chartr EP icon) to restart the application. If database problems continue, contact GN Otometrics Customer Support.

8 Safety

This Installation and Startup Guide contains information and warnings, which must be followed to ensure the safe performance of ICS Chartr EP 200. Local government rules and regulations, if applicable, should also be followed at all times.

8.1 Symbols Used

ICS Chartr 200 Symbols

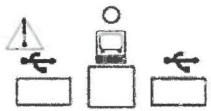
	ICS Chartr EP 200 is marked with this symbol to indicate compliance with Type BF of the safety standard EN 60601-1.
	ICS Chartr EP 200 is marked with this symbol when it is important that the user refers to associated information given in this manual.
CE XXXX	ICS Chartr EP 200 is CE-marked according to the Medical Devices Directive 93/42/EEC.

	The switch alternates between On and Stand-by mode. Green – the switch is On (pushed in) and the USB connection unit is ready. Blue – the switch is in Stand-by mode (pushed in) with no USB connection. Clear – the switch is Off (pushed out).
	The instrument is marked with this symbol to indicate that it is electronic equipment covered by the Directive 200296/EC on waste electrical and electronic equipment (WEEE).
	Chartr EP(USB) is marked with this symbol to indicate it is suitable for direct current.
	Symbols on the Chartr EP (USB) back panel, see 10.1.1 Chartr EP (USB) Back Panel ▶ 118.

8.2 Warning Notes

ICS Chartr EP 200 Warning Notes

GN Otometrics ICS Chartr products are not designed to be used in conjunction with any devices not approved by GN Otometrics. Summation of combined unapproved parts could result in increased electrical leakage. All parts of the ICS Chartr EP 200 system are suitable for use within the patient environment.

	Equipment connected to the displayed connectors must be certified to relevant EN/IEC safety standards, e.g., EN/IEC 60950. Mains connected equipment – except EN/IEC 60601-1 certified equipment – must be powered from isolation transformer.
	Equipment connected to the displayed connectors must be certified to relevant EN/IEC safety standards, e.g., EN/IEC 60950. Mains connected equipment – except EN/IEC 60601-1 certified equipment – must be powered from isolation transformer.
	Equipment connected to the displayed connectors must be certified to relevant EN/IEC safety standards, e.g., EN/IEC 60950. Mains connected equipment – except EN/IEC 60601-1 certified equipment – must be powered from isolation transformer.
	The Chartr EP (USB) should only be connected to power adapter type FW73623M/15 from Friwo. For continued protection against fire hazard, replace fuse with the same type and rating only.

Equipment

Note 1:

There are no user-serviceable parts inside the Chartr EP (USB) box. For the sake of safety, and in order not to void the warranty, the cabinet should only be opened and serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective instrument.

Note 2:

Keep ICS Chartr EP 200 away from liquids. Do not allow moisture inside the instrument.

Note 3:

Do not use the instrument in the presence of flammable anesthetics (gases).

Note 4:

Unwanted noise may occur if ICS Chartr EP 200 is exposed to a strong radio field. Such noise may interfere with the process of recording correct measurements. Many types of electrical devices, e.g., mobile

telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of ICS Chartr EP 200 is restricted as much as possible.

Note 5:
It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.

Note 6:
No parts may be eaten, burnt, or in any way used for purposes other than evoked potential testing.

Note 7:
ICS Chartr EP 200 can be disposed of as normal electronic waste, according to local regulations.

Note 8:
For safety reasons, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.

Note 0:
To comply with EN 60601-1-1, the computer, printer, etc. must be connected to the isolation transformer.

Note 10:
Connection to network or modem components may compromise the safety or effectiveness of this system. Use fiber-optic or wireless network connections to install the computer on a network.

Note 11:
The device is disconnected from the mains by removing the plug of the isolation station from the wall outlet.

Note 12:
Avoid accidental contact between connected but unapplied parts (electrodes including connections) and other conductive parts including those connected to protective earth.

Isolation Transformer (Powertronix Isolation Station)
Note 13:
The isolation station should not be placed on the floor.

Note 14:
The isolation station should be plugged directly into an outlet. Extension cords or power strips should not be used in combination with the isolation station.

Note 15:
Only the Chartr EP (USB) power supply, laptop/computer power supply, and deskjet printer power supply hould be connected to the isolation station. Do not connect any other devices to the isolation station. Connecting other equipment to the isolation station can overdrive the isolation station resulting in a blown fuse or damaging the isolation station beyond repair.

Note 16:
Do not connect the Chartr EP (USB) system directly to the wall outlet. By not using the isolation station, you put the patient at risk to be exposed to power surges or electrical shock.

Patient Care

Note 17:
Do not touch non-medical parts, such as the laptop/computer or printer and the patient at the same time.

Note 18:
Do not allow electrodes or electrode leads to contact conductive parts of the equipment or the earth.

Note 19:
While the patient who has a pacemaker or other implantable device is not at harm during testing, these devices may interfere with the process of recording correct measurements.

Note 20:
Exposure to electromagnetic fields can result in interference with the process of recording correct measurements. TheChartr EP (USB) amplifiers are sensitive to electrical disturbances. Avoid static discharges and electromagnetic fields.

Note 21:
Conductive parts with patient connection must not be in contact with other conductive parts at any time. No defibrillators or high-frequency surgical equipment should be applied to the patient when connected to the Chartr EP (USB) at any time. Connecting a patient to high-frequency surgical equipment while using the Chartr EP (USB) may result in burns at the site of the electrode contacts.

Note 22:
Immediately discontinue device use if skin irritation or discomfort occurs.

8.3 Guidance and Manufacturer's Declaration Tables

8.3.1 Electromagnetic Emissions

Chartr EP 200 is intended for use in the electromagnetic environment specified below. The customer or user of Chartr EP 200 should ensure that it is used in such an environment.

Emissions test	Compliance level	Electromagnetic environment – Guidance
RF Emissions CISPR 11 / EN55011	Group 1	Chartr EP 200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11 / EN55011	Class B	Chartr EP 200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

8.3.2 Immunity - All Equipment and Systems

Chartr EP 200 is intended for use in the electromagnetic environment specified below. The customer or user Chartr EP 200 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	Not applicable	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains	±2kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of Chartr EP 200 requires continued operation during power mains interruptions, it is recommended that Chartr EP 200 be powered from an uninterruptible power supply or battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment Guidance
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

8.3.3 Immunity - Life Supporting Equipment and Systems

Chartr EP 200 is intended for use in the electromagnetic environment specified below. The customer or user of Chartr EP 200 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance test	Electromagnetic environment-Guidance
			Portable and mobile communications equipment should be separated from the Chartr EP 200 by no less than the distances calculated/listed below:
Conducted RF IEC 61000-4-6	3 Vrms (Outside ISM)	(10)Vrms	$d = (3.5/3)(\sqrt{P})$ $d = 1.17(\sqrt{P})$

Immunity test	IEC 60601 test level	Compliance test	Electromagnetic environment-Guidance
	10 Vrms (in ISM bands) 150 kHz to 80 MHz	(10)Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	(10)V/m	d = (3.5/10)(√P) d = 0.35(√P) 80 to 800 MHz d = (7/10)(√P) d = 0.7(√P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

8.3.4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Chartr EP 200 - Life Supporting Equipment and Systems

Chartr EP 200 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of Chartr EP 200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and Chartr EP 200 as recommended below, according to the maximum output power of the communications equipment.

Maximum output power (Watts)	Separation (m) 150 kHz to 80 MHz Non-ISM d = (3.5/V1)(ÖP)	Separation (m) 150 kHz to 80 MHz ISM d = (12/V2)(ÖP)	Separation (m) 80 to 800 MHz d = (3.5/E1)(ÖP)	Separation (m) 800 MHz to 2.5 GHz d = (7/E1)(ÖP)
0.01	0.12	0.12	0.035	0.07
0.10	0.37	0.38	0.11	0.22
1.00	1.17	1.20	0.35	0.70
10.00	3.69	3.79	1.11	2.21
100.00	11.70	12.00	3.50	7.00

8.3.5 Manufacturer

GN Otometrics A/S
9 Hoerskaetten
DK-2630 Taastrup Denmark
T: +45 45 75 55 55, **F:** +45 45 75 55 59
www.otometrics.com

8.3.6 Responsibility of the Manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment ONLY IF:

- All assembly operations, extensions, re-adjustments, modifications, or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability, and performance of equipment serviced or repaired by other parties.

9 Technical Specifications

9.1 ICS Chartr EP 200

Interface

USB to PC

Type Identification

ICS Chartr EP 200 is Type 1073 from GN Otometrics A/S

Power Supply

AC/DC Adapter:	Type:	FW7362M/15 from Friwo
	Input:	100-240 VAC / 50-60 Hz / 400 mA
	Output:	15V DC / 2A

Powertronix Isolation Station
(supplied by GN Otometrics A/S)

Part number:	X1ATWFHNOC1

Input voltage:	115 (120) / 230 (240) VAC – 50/60 Hz
Input current:	2.6 A / 1.3 A
Leakage current:	< 100 µA
Output voltage:	115 (120) / 230 (240) VAC
Output current:	2.5 A / 1.25 A

9.2 System Capabilities

Performance characteristics

Analysis time:	5.0 – 9000 msec
A/D resolution:	16-bit
Artifact rejection:	100% full scale
Points per trace:	600

Amplifiers

Channels:	2 (the third channel is used for VEMP monitoring)
Gains:	X1000 – X500000

Analog Filters

Low pass:	15 Hz to 10 KHz, 12 dB/octave
High pass	0.2-1 kHz, 6 dB/octave

Miscellaneous

Noise level:	<1.5uV RMS (0.1 Hz – 5KHz)
Input impedance:	>10 MOhm
CMR ratio:	>100 dB at 50/60 Hz
Impedance ratio:	internal, 20 Hz triangular wave

Stimulators

Stimuli:	Click, tone burst

Parameters for tonal stimuli:	Programmable – frequency, intensity, rise/fall time, plateau duration, envelope shape
Rate:	0.2 to 180/sec
Intensity:	0 dB to + 132 dB SPL
Masking:	White noise, programmable
Transducers:	TDH-49 earphones, insert earphones, bone conduction transducer
Software:	Windows Graphical User Interface; High Performance Analysis Software; Database Storage of Test Data; Patient and Test Data Management
Data collection:	Tests impedance of patient's electrode connections, displays waveform during collection, displays ongoing EEG, stores waveforms, presents normative data graphs, and tone burst threshold plots.
Ancillary functions:	Database archive, import, and export.

Operating Mode

Warm-up time:	<2 min
Mode of operation:	Continuous

Operating Environment

Temperature:	+15° C to +35° C (59° F to +95° F)
Rel. Humidity:	30 to 90%, non-condensing
Air Pressure:	600 hPa to 1060 hPa

Operations at temperatures below -20 °C or above +60 °C may cause permanent damage.

Storing and Handling

Temperature:	0° C to +40° C (32° F to +104° F)
Rel. Humidity:	<90%, non-condensing
Air Pressure:	500 hPa to 1060 hPa

Dimensions

Chartr EP (USB) (HxWxD)	4.9 cm x 34.2 cm x 28.7 cm (2" x 13.6" x 11.3")
Preamp (HxWxD)	3.0 cm x 9.9 cm x 16.4 cm (1.19" x 3.88" x 6.44")
VEMP monitor (HxWxD)	2.9 cm x 6.2 cm x 9.5 cm (1.13" x 2.44" x 3.75")

Weight

Chartr EP (USB) box	2.7 kg (5 lbs 7 oz)
PreAmp	0.3 kg (10.6 oz)
VEMP Monitor	0.13 kg (4.5 oz)

Calibration

None required, but recommended annually

Standards

Safety:	EN 60601-1, UL2601-1, CAN/CSA-C22.2 NO 601.1-90	
	Chartr EP (USB)	EN 60601-1, Class II, Type BF, IPXO½
	Power Supply	EN 60601-1, Class II, IPXO
System:	EN 60601-1-1	
EMC:	EN 60601-1-2	

ASSR Specifications

Transducer:	Insert earphones, headphones, bone oscillator
AM depth:	50 – 100%, in 5% steps
FM depth:	0 – 25%, in 5% steps
Threshold search / upper limit:	0 – 120 dB HL (insert phones) 0 – 110 dB HL (headphones) 0 – 60 dB HL (bone oscillator) 5 dB steps
Threshold Search / lower limit:	Same options as upper limit
Minimum step size:	5 or 10 dB HL
Channel gain:	Standard Chartr settings
High Pass / Low filters:	Exclusive Chartr narrow filters for RapidASSR™ Standard Chartr settings
Per ear / frequencies to test:	250, 500, 1000, 2000, 4000, 8000 Hz
Per frequency tested, per ear modulation frequency:	20 – 105 Hz, in 1 Hz steps

Response search time: Test impedance of patient electrode connections, displays waveform during collection, displays ongoing EEG, stores waveforms, presents corrected and uncorrected tone threshold plots.

ICS Chartr EP 200 Starter Kit

Standard Accessories:

Nuprep, 4 oz tubes, pkg/3
(1 tube supplied in starter kit) – 7590030-3

Five snap lead package, 24" length – 7590319-24-5

Snap disposable electrodes – 8-64-21602

Gold electrodes 5 leads – 7590450-5

Individual jumper – 7590490

Gauze sponge pads 2 x 2" – 8-62-43000

Skin prep Qtips – 8-62-43001

Ten 20, pkg/3
(1 tube supplied in starter kit) – 7590480-3

Infant silicon tips – 7590506

Adult foam eartip, 13 mm – 80A4820900

Adult jumbo foam eartip, 18 mm – 80A4821100

Pediatric foam eartip, 10 mm – 80A4821000

ICS Chartr EP 200, VEMP Starter Kit

Differential disposable electrodes – 8-64-21600

Additional snap leads:

- 7590312-24 (green)
- 7590313-24 (brown)

10 Installation Reference

The Installation Reference section provides information needed during set up of the ICS Chartr EP 200 equipment. It includes the following topics:

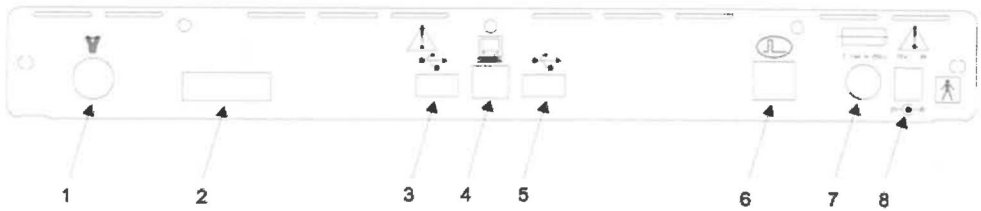
- Set up the Hardware
- ICS Chartr EP 200 Remote Control
- Software Overview
- Set up the Test Site Facility Information
- Establish Normal Hearing Level Thresholds

If you need additional information or are experiencing problems, refer to the Troubleshooting section in this guide and the *ICS Chartr EP User Manual.*

10.1 Set up the Hardware

10.1.1 Chartr EP (USB) Back Panel

The components on the Chartr EP (USB) back panel are shown on the following diagram.

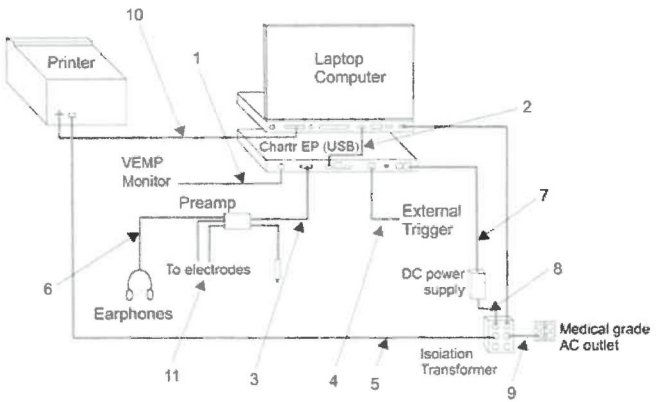


Chartr EP (USB) Back Panel

	Description/Function
1	VEMP monitor
2	Preamp
3	USB
4	PC (laptop)
5	USB
6	External trigger
7	Power input fuse
8	DC power input

10.1.2 ICS Chartr EP 200 Hardware Connections

The ICS Chartr EP 200 hardware consists of the PC, keyboard, monitor, preamplifier, printer, and interconnecting cables (connections shown on diagram).



ICS Chartr EP 200 System Connections

Hardware Interconnection List	
1	VEMP Monitor cable to VEMP port
2	USB cable between laptop computer and Chartr EP (USB)
3	Preamp cable to Preamp
4	External trigger cable to ICS Chartr EP(USB)
5	Printer power cord to isolation transformer
6	Earphone cable to preamp
7	Power cable to DC power supply
8	DC power supply cable to isolation transformer
9	Isolation transformer cable to AC outlet
10	Printer cable to printer port
11	Electrode cables to preamp

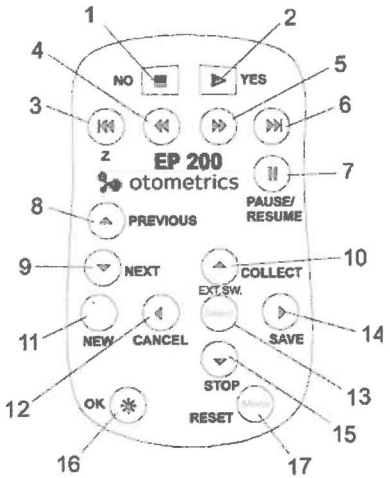
When ICS Chartr EP 200 system starts for the first time, a Workstation name dialog box displays. Type a unique name that will identify the workstation and click OK.

Network considerations

Use fiber-optic network connections to install data acquisition workstations on a network. This will preserve the patient's electrical isolation.

10.2 Chartr EP (USB) Remote Control

The wireless remote control consists of a transmitter and a keypad. The keypad allows the operator to remotely operate many of the EP data collection activities without using the software function keys.



Remote Control Keypad

	Description/Function
1	No
2	Yes
3	Impedance
4 – 6	Not used
7	Pause / Resume
8	Previous Page
9	Next Page
10	Collect
11	New Test / Review
12	Cancel
13	Extend Sweeps
14	Save
15	Stop
16	OK
17	Reset

10.3 Software Overview

ICS Chartr EP is an easy-to-use auditory evoked potential (EP) system that operates in a Windows operating system environment.

Use a mouse or keyboard to communicate with the software.

- Use the Function keys (F1 to F12) and menus to select options.
  - Click on a **Function** key to activate the option.
  - Click on a Menu then click on a menu option. You may also press the Alt key and an **underlined letter** on the Menu bar.
- To close a window or dialog box:
  - Click the **Close** or **Exit** button on the window or dialog.
  - Click the **Close** button on the upper-right side of the window or dialog.
  - Click **File > Close** or **Exit** on the Menu bar.

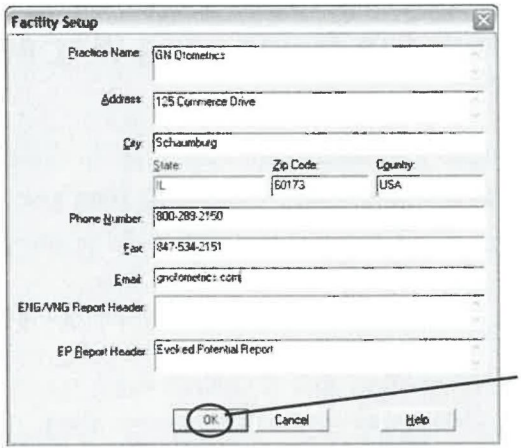
To shut down the PC:

1. Close all open applications and return to the Windows Desktop.
2. Click **Start** on the Taskbar and select **Shut Down**.
3. Select the **Shut Down the computer?** option and click **Yes**.

10.4 Set up the Test Site Facility Information

Add the test site facility information to the database so that it can be used as needed by the program. For example, patient reports include the test site facility name and address.

1. Select **Setup > Edit Facility Info** to display the Facility Setup dialog.
2. Type the test site facility information.



Facility Setup Dialog Box

A. Type this information:
- Practice (facility) Name [required]
- Address
- City
- State, Zip Code, Country
- Telephone Number
- Fax number
- Email address
- VNG/ENG Report Header (use only if ICS Chartr VNG/ENG software is installed on the PC)
- EP Report Header

B. Click **OK**.

3. Click **OK** to save the information.

10.5 Establish Normal Hearing Level Thresholds

A test facility may use the default normal hearing level thresholds or establish facility-specific normal hearing level thresholds. The thresholds are established by conducting a series of tests on normal hearing adults using facility equipment. Use this procedure to enter the facility threshold values in ICS Chartr EP.

Once the biological calibration (i.e., listening check) is performed and correction value is determined, then changes can be made in the Normal Hearing Level Thresholds.

If the softest level normal hearing people hear is 20 dB, add this value to the value in the system (i.e., click would change from 0 to 20). This makes 0 dB on the dial equal to 0 dB. This will reduce the maximum output from what it was before the change was made. You will not have a correction factor if the change is made.

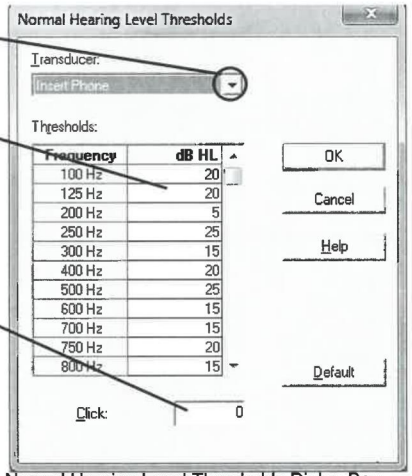
1. Select **Calibration > Normal Hearing Level Thresholds** from the Menu bar to display the **Normal Hearing Level Thresholds** dialog box.

2. Select a transducer and type the new values.

A. Click and select a transducer from the list.

B. Type the facility dB HL values.

C. Type the facility Click value.



Normal Hearing Level Thresholds Dialog Box

3. Click **OK** to save the new values.

11 Diagnostic Calibrations

For Authorized Distributor Use Only

11.1 Calibrate Hardware after Installation

All ICS Chartr EP 200 systems are calibrated at GN Otometrics prior to shipment. However, Normal Hearing Level Thresholds (dB nHL) can be modified as part of the system setup.

After the initial installation and calibration, hardware components should be calibrated annually and as needed when system components are replaced or if the operating environment changes. See the *ICS Chartr EP User Manual* for more information.

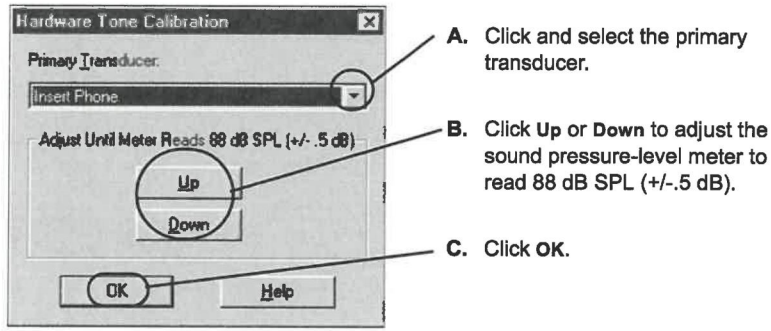
Use the Setup Menu (when patient records are closed) to access the Calibration options.

Calibration
Hardware Tone Calibration...
ASSR Hardware Calibration...
Frequency-Specific Tone Calibration...
Hardware Masking Calibration...
ANSI Hearing Level Thresholds...
Normal Hearing Level Thresholds ...
nHL/SPL Conversion Table...
ASSR Audiogram Correction Factors...
Export Tone...
Import Tone...

11.2 Calibrate Hardware and Frequency-Specific Tones

Tonal stimuli calibration is completed at 1-kHz in the primary transducer using a Type 1 sound pressure-level meter and is followed by a frequency-specific tone calibration.

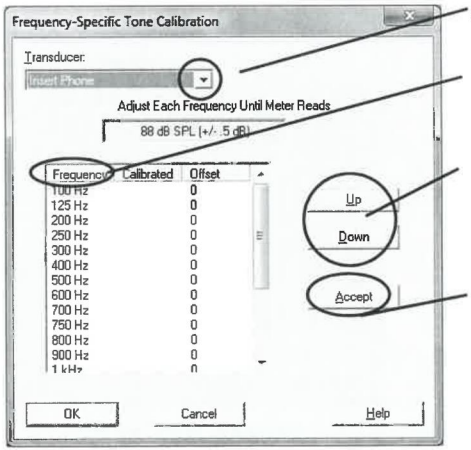
1. Set up the left transducer (blue insert earphone, blue headphone, or bone conductor) and the artificial ear (2cc or 6cc coupler or artificial mastoid) with a sound pressure-level meter according to the manufacturer's instructions.
2. Select **Calibration > Hardware Tone Calibration.**
3. Calibrate the hardware tone.


Hardware Tone Calibration
Primary Transducer
Insert Phone
Adjust Until Meter Reads 88 dB SPL (+/- .5 dB)
Up
Down
OK
Help
A. Click and select the primary transducer.
B. Click Up or Down to adjust the sound pressure-level meter to read 88 dB SPL (+/-.5 dB).
C. Click OK.

Hardware Tone Calibration Dialog Box

4. Click **OK** to save the tonal calibration and display a message.
5. Click **OK** to display the Frequency Specific Tone Calibration dialog.

6. Calibrate a frequency-specific tone.



A. Click and select a transducer.

B. Select a frequency.

C. Click **Up** or **Down** to adjust the sound pressure-level meter to read **88 dB SPL (+/-.5 dB)**.

D. Click **Accept** to save the calibration and put an X in the Calibrated column.

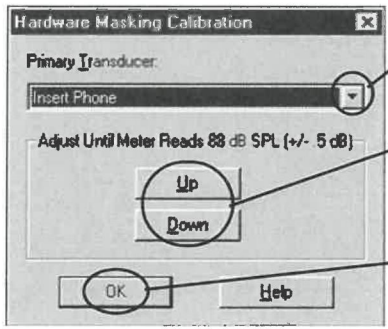
Frequency-Specific Tone Calibration Dialog Box

7. Repeat step 6 for each frequency you want to calibrate.
8. Repeat steps 6 and 7 for each transducer used at your facility.
9. Click **OK** to close the dialog.

11.3 Calibrate Hardware Masking

Use a sound pressure-level meter to calibrate the masking level produced by the system when the system is installed and as needed.

1. Set up the left transducer (insert earphone, headphone, or bone conductor) and the artificial ear (2cc or 6cc coupler or artificial mastoid) with a Type 1 sound pressure-level meter according to the manufacturer's instructions.
2. Select **Calibration > Hardware Masking Calibration.**
3. Calibrate the hardware masking level.


Hardware Masking Calibration
Primary Transducer:
Insert Phone
Adjust Until Meter Reads 88 dB SPL (+/- 5 dB)
Up
Down
OK
Help
A. Click and select the primary transducer.
B. Click Up or Down to adjust the sound pressure-level meter to read 88 dB SPL (+/-.5 dB).
C. Click OK.

Hardware Masking Calibration Dialog Box

4. Click **OK** to save the calibration.